Exhibit A

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Tarler

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(54) **ELECTRODE PATCH AND WIRELESS PHYSIOLOGICAL MEASUREMENT SYSTEM AND METHOD**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 64 days.

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(22) Filed: **Jun. 29, 2004**

(51) **Int. Cl.**
A61B 5/04 (2006.01)
A61B 5/0452 (2006.01)

(52) **U.S. Cl.** **600/509**; 600/508; 600/372; 600/393; 600/301; 128/903

(58) **Field of Classification Search** 600/508–509, 600/545–546, 393–396, 372–373, 382–384, 600/301; 128/903
See application file for complete search history.

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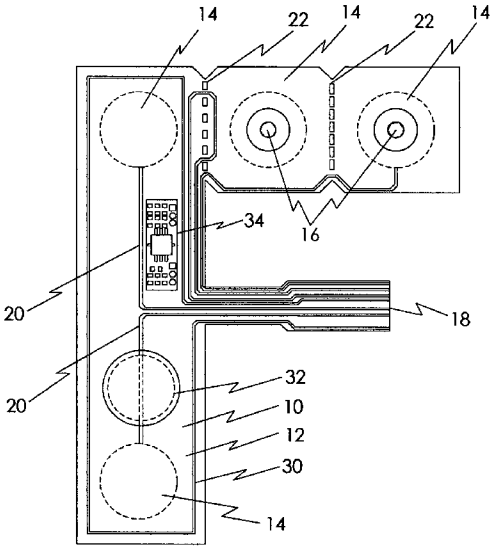
(57) **ABSTRACT**

A wireless electrode patch and system for measuring the physiological condition of a subject, more particularly to an electrode patch for ECG monitoring, and a method of sensing, analyzing and/or transmitting or relaying a physiological signal. The wireless electrode patch and system is lightweight, compact and reusable. The wireless electrode patch provides a low, power system for extended battery life and use. The wireless electrode patch and system allows for good reliable measurement of physiological signals from the subject. The wireless electrode is simple enough to apply as a single patch but versatile enough to be reconfigured as more than one patch.

18 Claims, 12 Drawing Sheets



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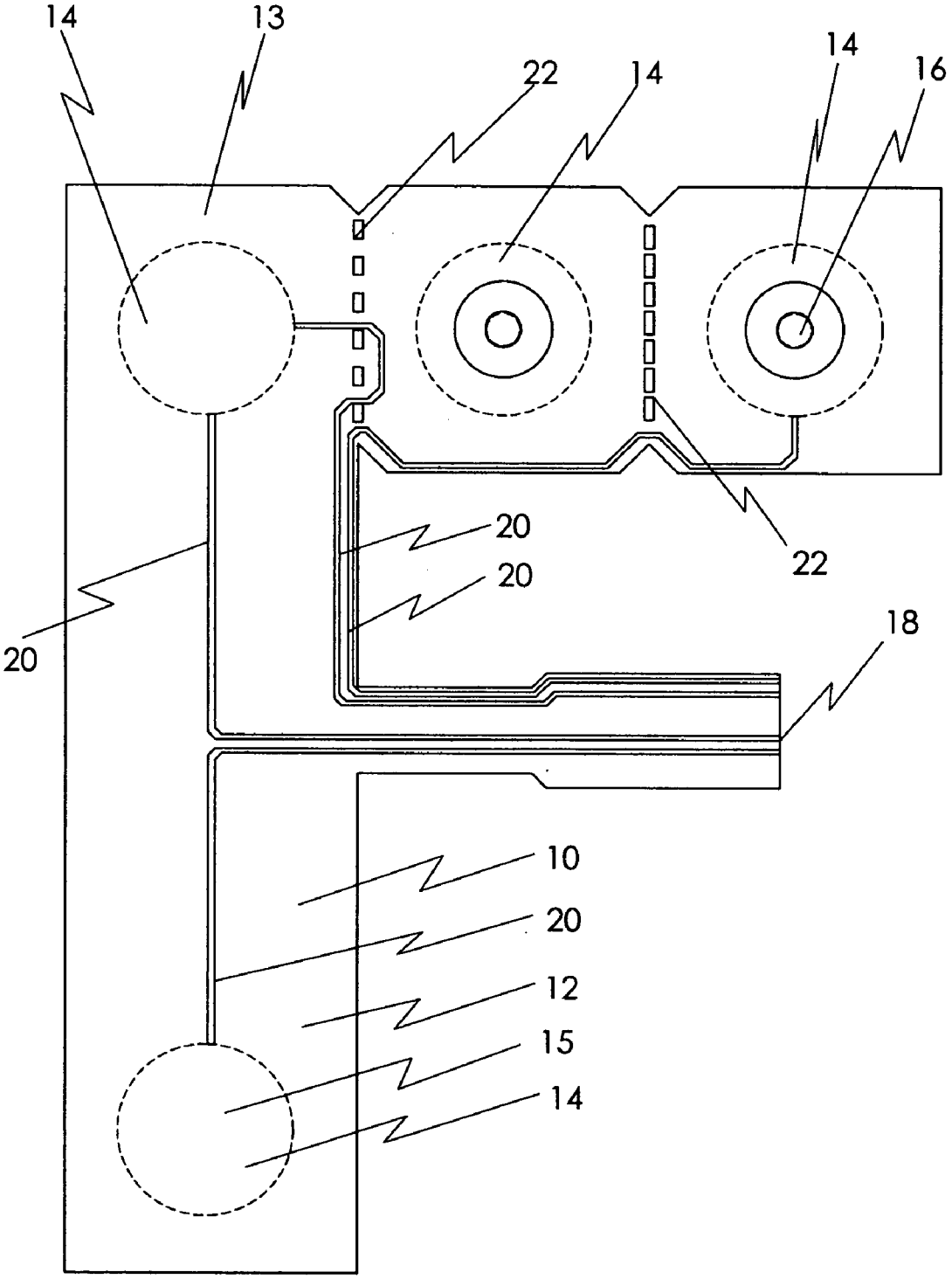

Fig 1

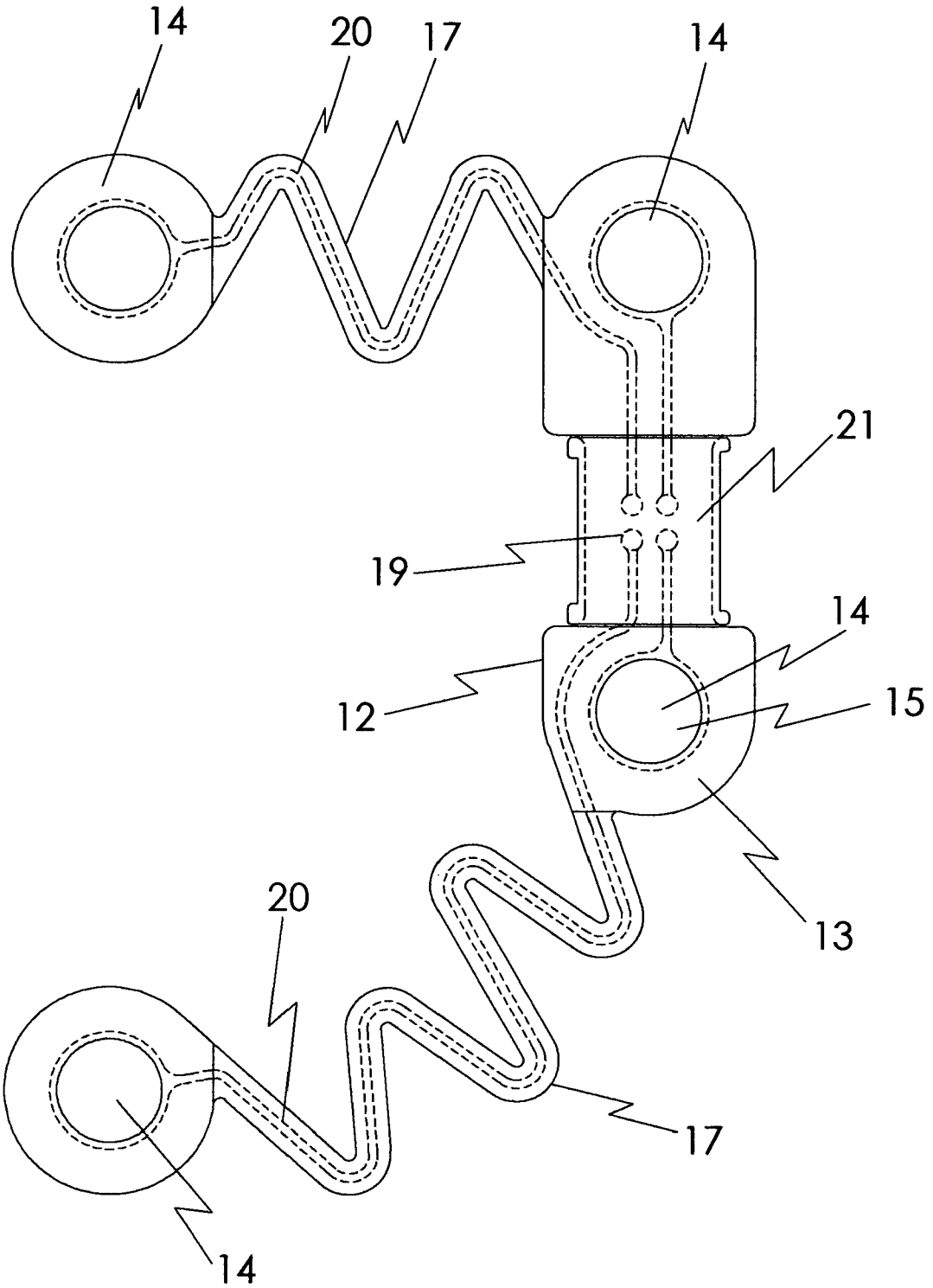

FIG 2

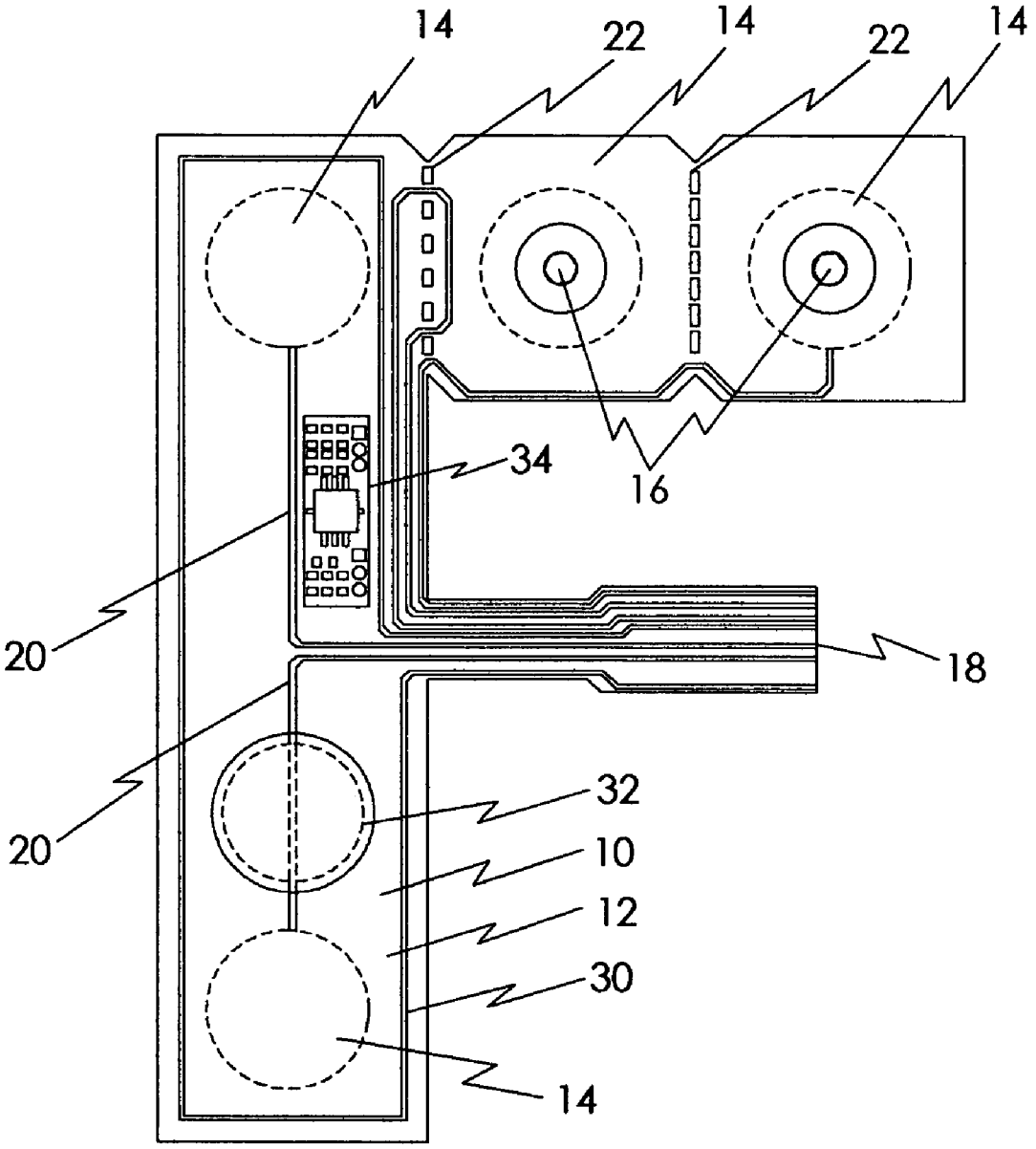

Fig 3

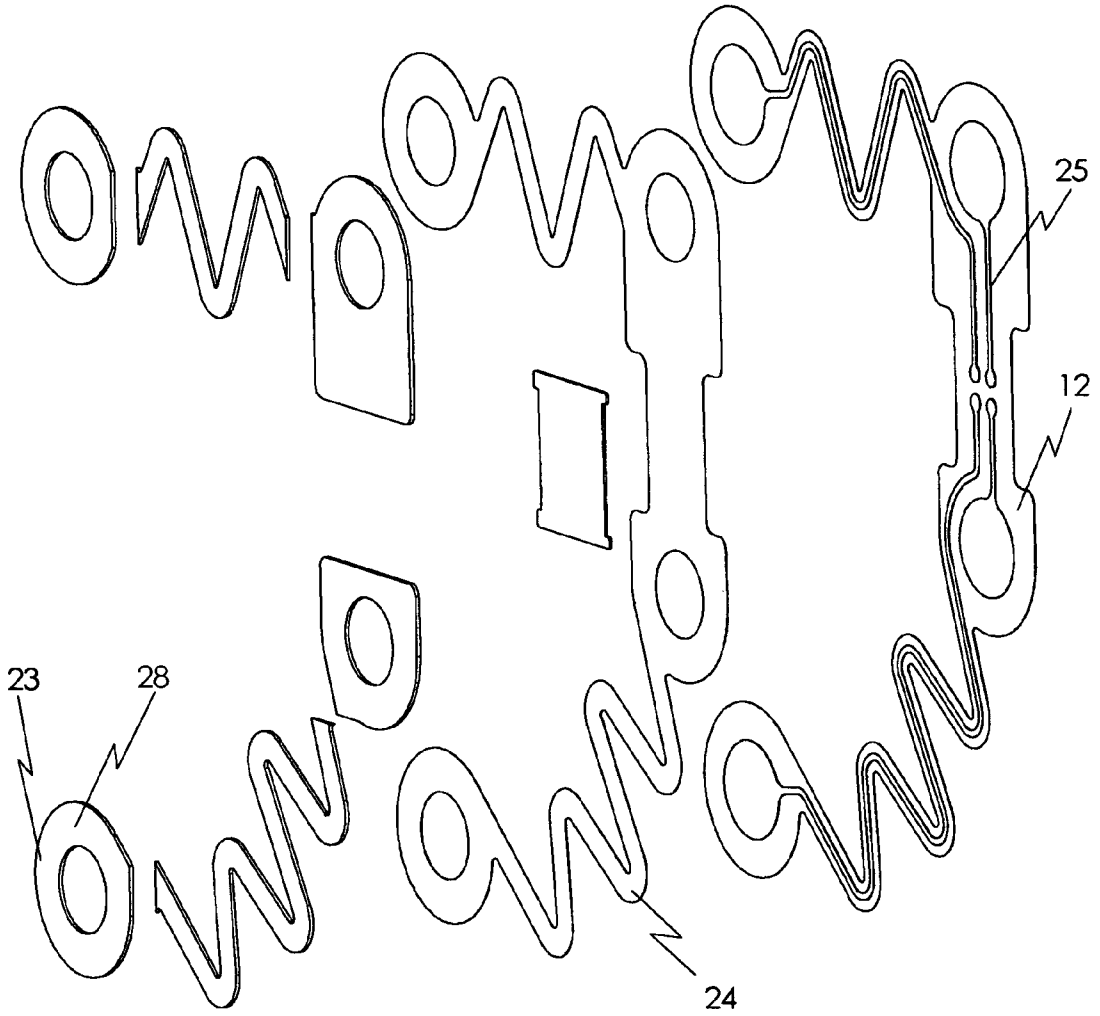

FIG 4

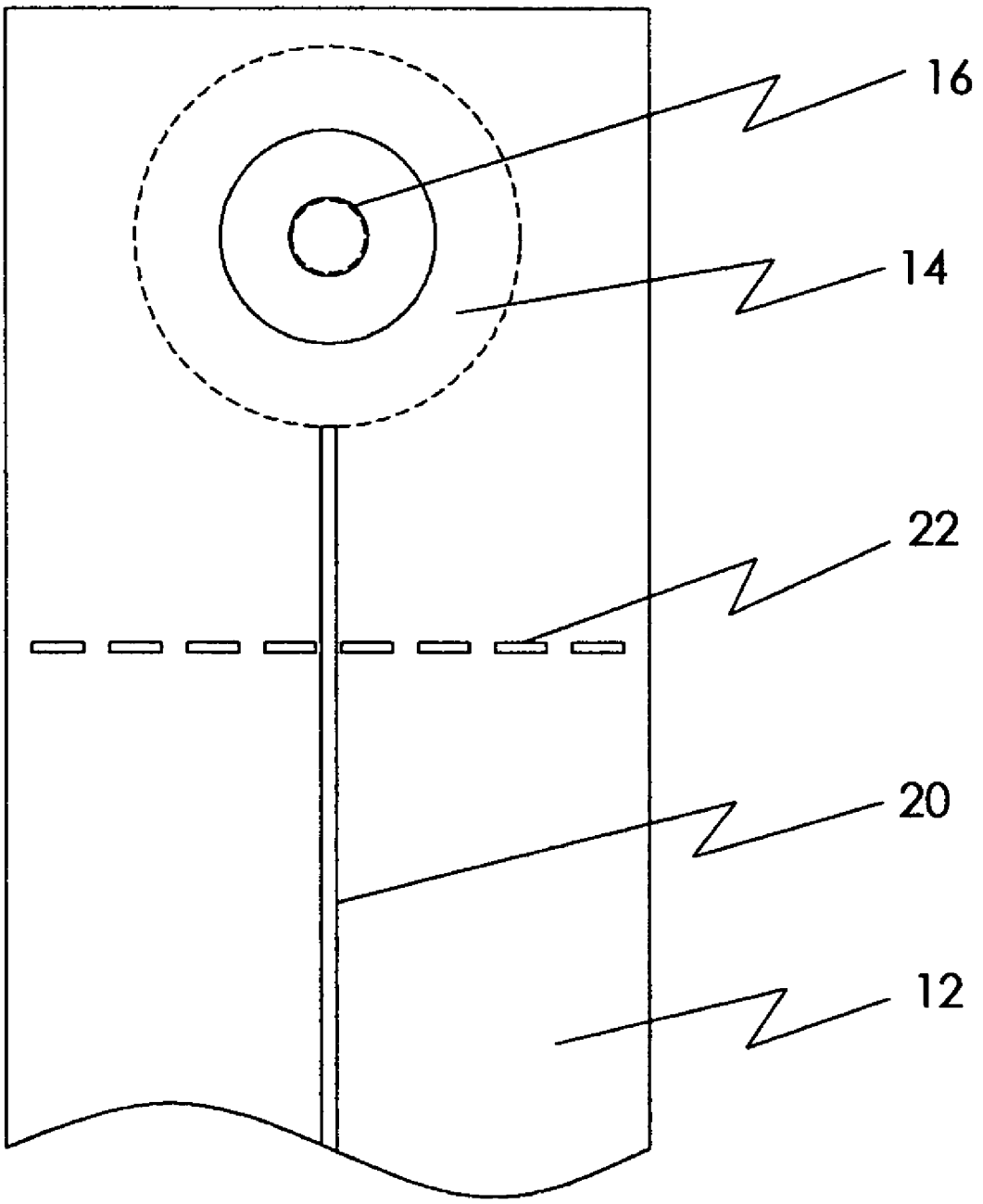

Fig 5A

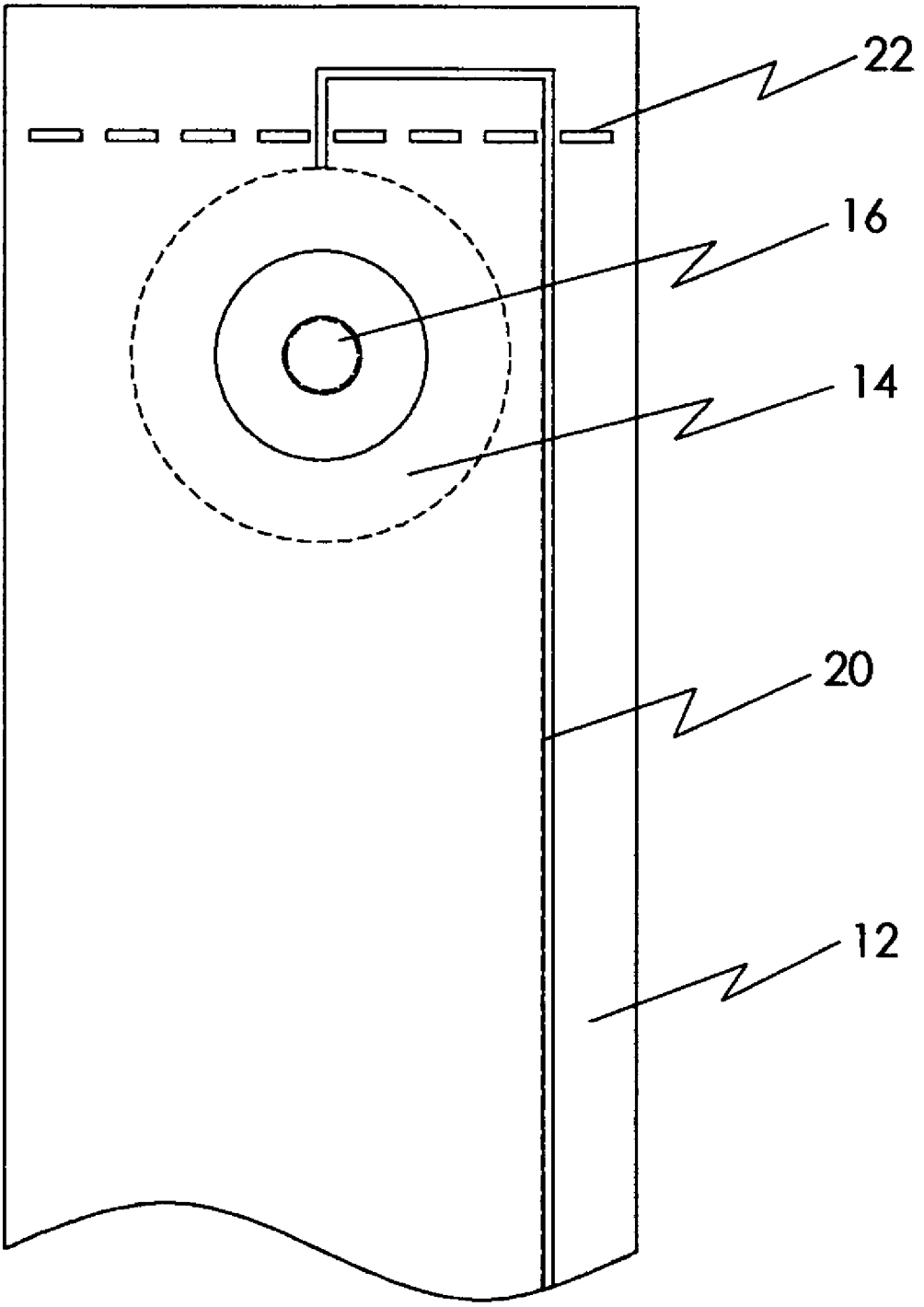

Fig 5B

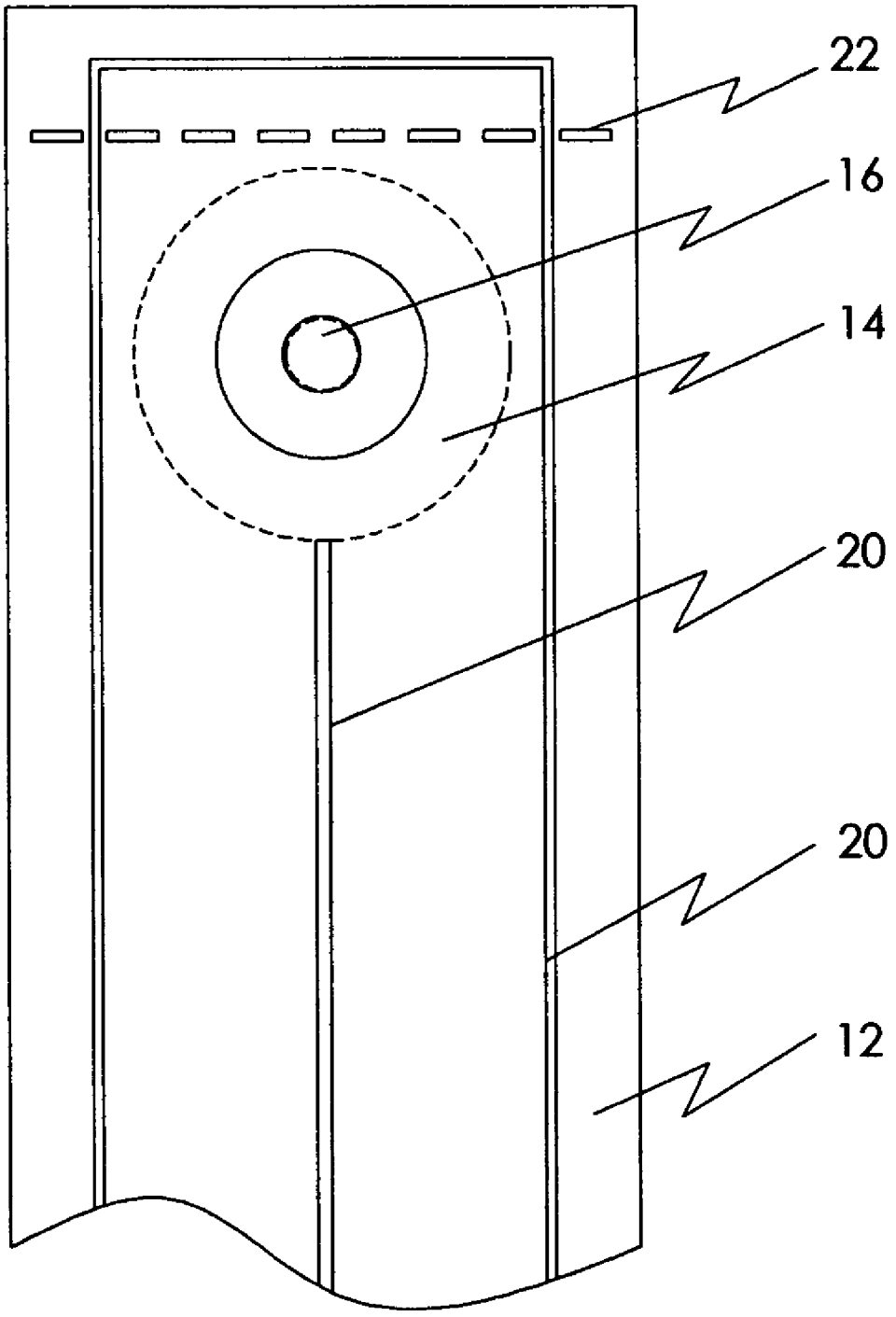

Fig 5C

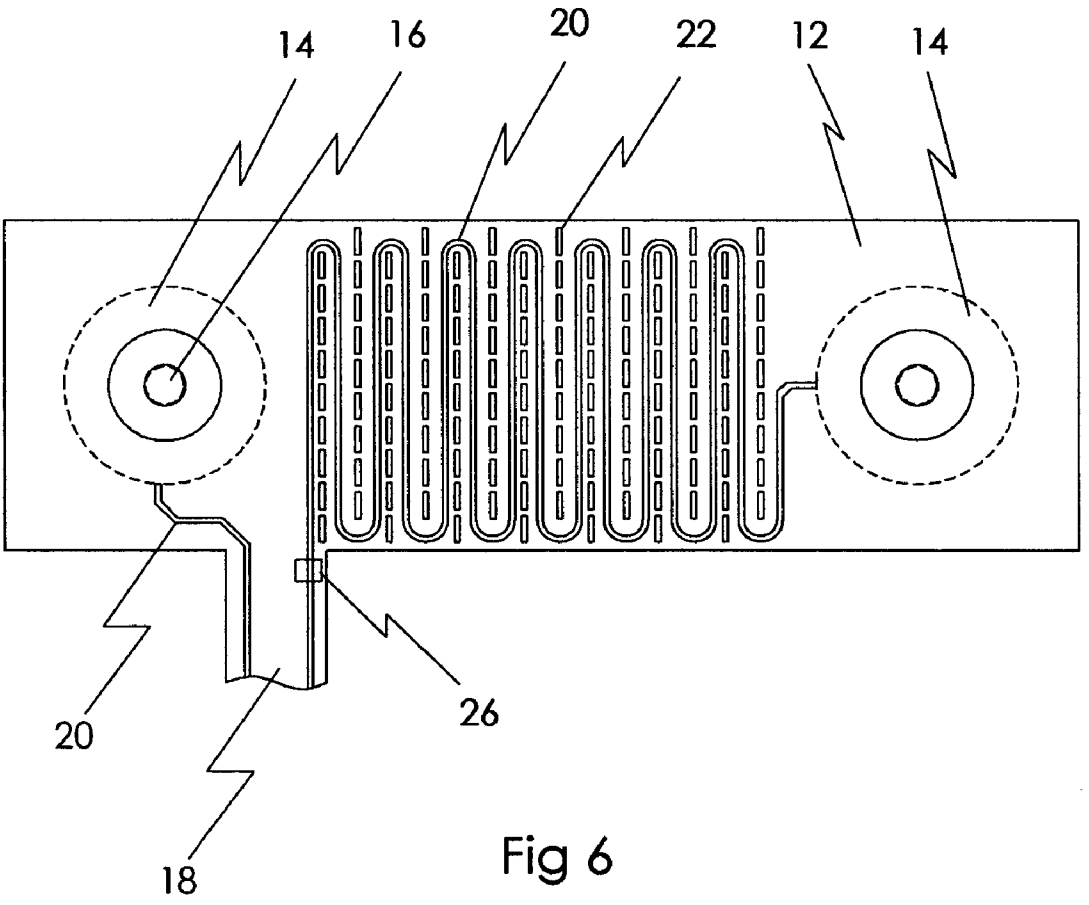

Fig 6

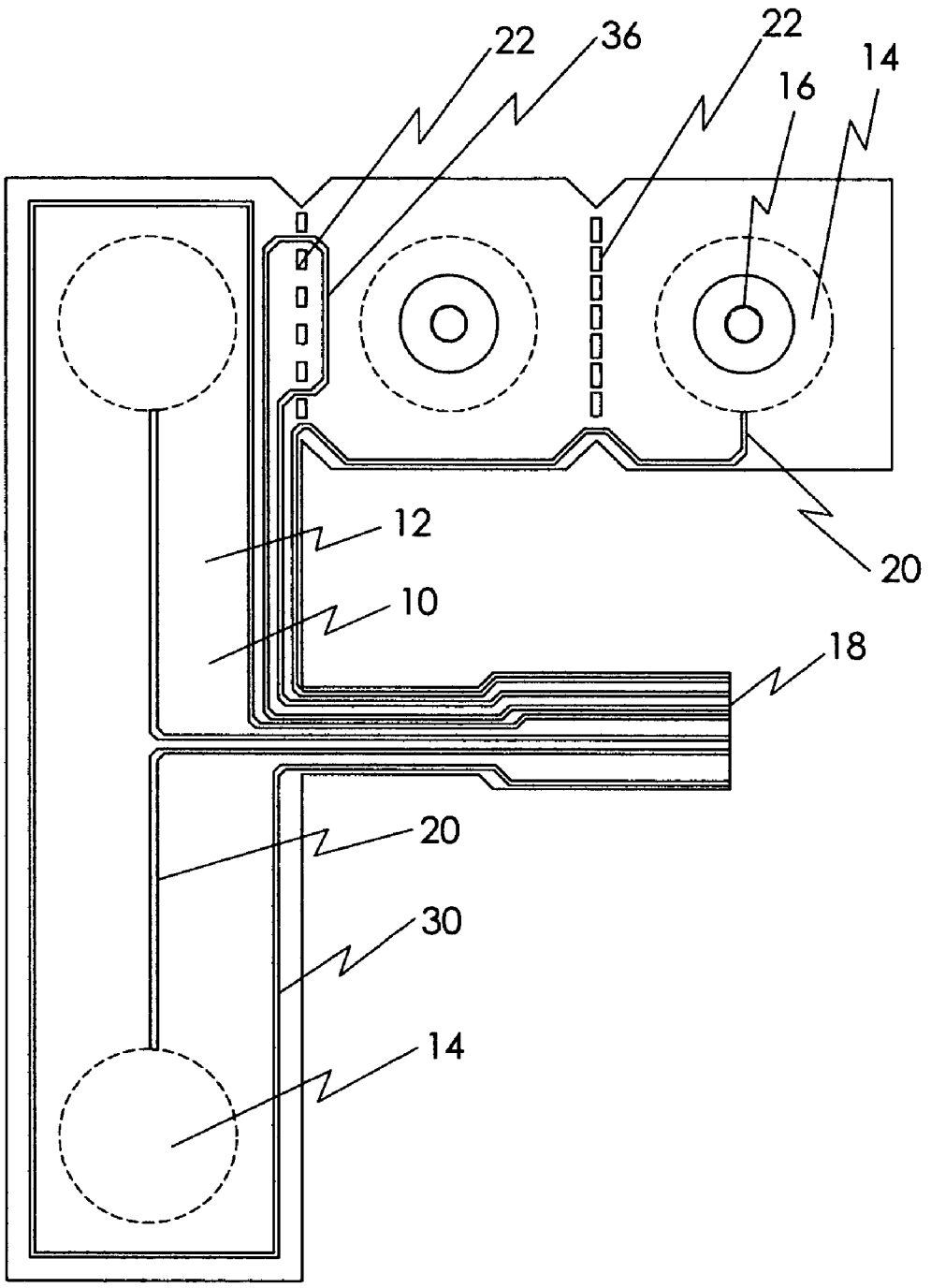

Fig 7

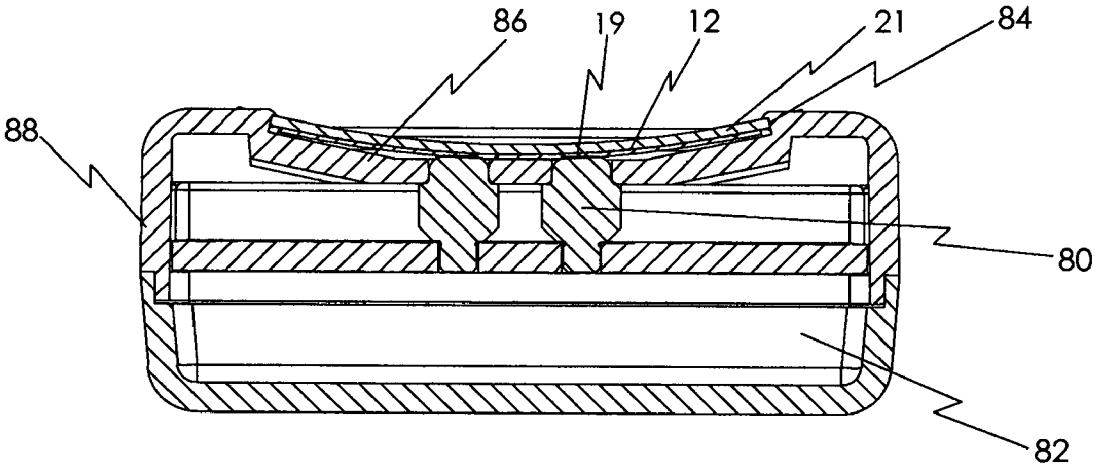

FIG 8

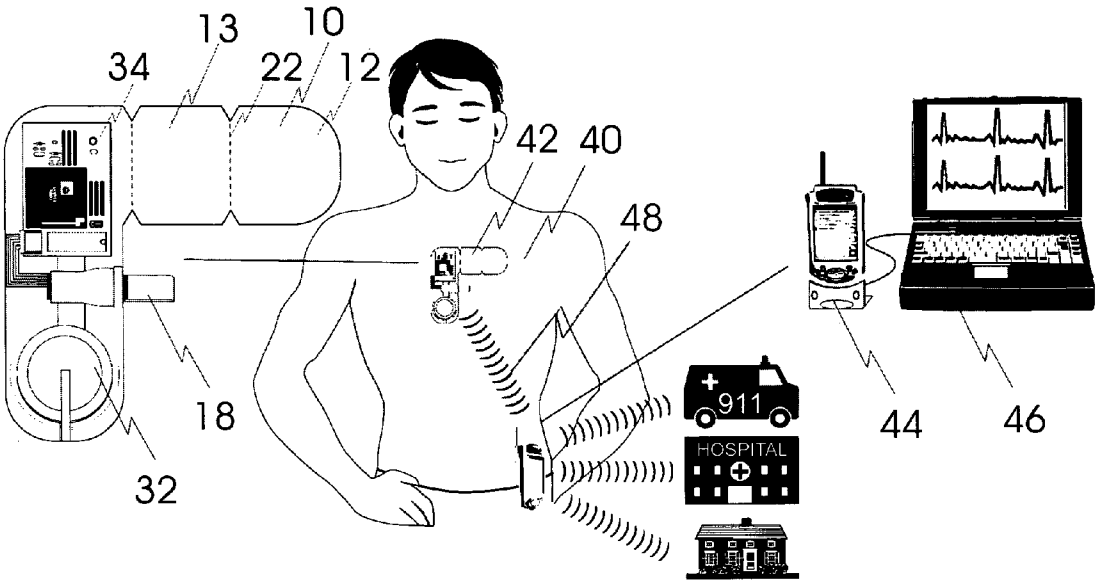

Fig 9

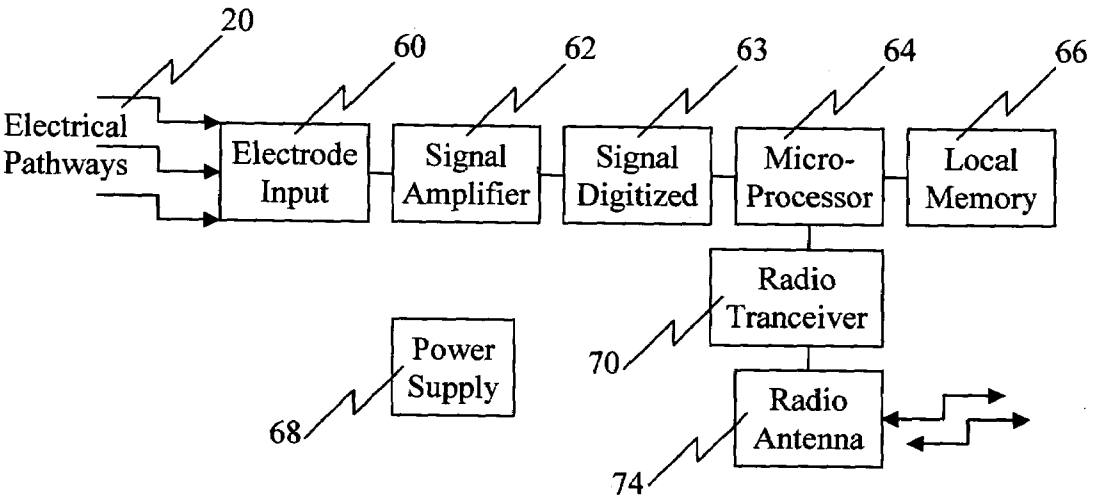
20
60
62
63
64
66
Electrical Pathways
Electrode Input
Signal Amplifier
Signal Digitized
Micro-Processor
Local Memory
Radio Tranceiver
70
Power Supply
68
Radio Antenna
74

Fig 10

ELECTRODE PATCH AND WIRELESS PHYSIOLOGICAL MEASUREMENT SYSTEM AND METHOD

The U.S. Government has a paid-up license in this invention and the right in limited circumstances to require the patent owner to license others on reasonable terms provided for by the terms of grant number 5R44HL065024-03 awarded by the National Institutes of Health.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention is related, in general, to an electrode patch and/or a wireless system for measuring the physiological condition of a subject, and more particularly to an electrode patch for ECG monitoring. The present invention further includes a method of sensing and analyzing a physiological signal.

2. Technical Background

Monitoring one or more physiological conditions of a patient is well known. Medical patient monitoring systems are highly sophisticated utilizing telemetry systems at a central receiving and monitoring station. ECG monitoring has the greatest applications.

According to present estimates, approximately 60 millions Americans have one or more types of cardiovascular disease including high blood pressure, coronary artery disease, stroke, rheumatic heart disease, congenital cardiovascular defects and congestive heart failure. Cardiovascular disease claims approximately one million lives in the United States each year, or approximately forty percent of all deaths. Since 1990, cardiovascular disease has been the number one killer in the United States every year other than 1918. More than 2,600 Americans die each day of cardiovascular disease, which is an average of 1 death every 33 seconds.

Because heart performance can deteriorate quickly, the key to effective cardiovascular disease management resides in early medical intervention. Patients often to not recognize subtle changes in cardiovascular disease symptoms and may not appreciate the importance of quickly reporting such changes to their physician. To make early intervention possible and prevent rehospitalization, healthcare providers need daily access to accurate information about patients' symptoms. There are many reasons a physician may want to monitor patients on a continuous or nearly continuous basis. These include the need to detect episodic arrhythmias, either to establish a diagnosis or to evaluate efficacy of therapy; the need to help evaluate syncope, in particular to detect any associated cardiac rhythm disorder or to assess therapy; the need to assess efficacy of therapy for atrial arrhythmias (this is especially important with atrial fibrillations in patients at risk for stroke or systemic embolism who can not take warfarin or similar drugs); the need in patients at increased risk for sudden arrhythmic death, particularly for example those patients with ventricular dysfunction who would benefit from prolonged (6 weeks to 6 months) ECG monitoring after serious events such as a myocardial infarction, an episode of cardiac decompensation, recent cardiac surgery or the onset of new therapy with an antiarrhythmic agent; and the need for providing patients with at home immediate access to 911 emergency help without patient action particularly for those patients who have had multiple myocardial infarctions.

A typical diagnostic process for any of these cardiovascular conditions may include one or more of the following tests: ECG; Holter monitor; external loop recorder; implantable loop recorder; tilt table test; electrophysiology study; and a stress test. An ECG can be performed in a physician's office or a hospital setting. It is unlikely, however, a patient will undergo many of the symptoms associated with these conditions such as for example syncope or fibrillation in those few minutes. A Holter monitor is a device that measures and records heart rhythm, usually over 1 day but occasionally for 2 or more days. Holter monitors can miss recording a critical moment when a diagnosis could be made because the event doesn't happen during the recording, or because the patient took the device off to sleep. This is particularly important where patients do not want to wear the device to work for fear of discrimination if their employer or fellow employees know they have a health problem. An external loop recorder is a device that monitors heart rhythm and rate for up to a month. During this test, the patient wears a device on the wrist, around the chest or in a pocket. The patient must press a button on the device to make a recording of the heart activity during the period the symptoms occur such as fainting. Unfortunately, this only occurs if the patient is sufficiently aware that the event took place. Furthermore, the information collected must be downloaded periodically making in more difficult for the patient to comply. Implantable loop recorders are relatively new devices. These devices suffer from these same drawbacks as well as the possibility of infection due to the invasive procedure used to implant the device. A tilt table test is used to simulate conditions that may cause fainting. It enables the physician to gauge how blood pressure, heart rate and rhythm respond to a change in position from lying down to standing. This test is expensive and is generally only done in a large or teaching hospital setting. An electrophysiology study is an expensive and invasive procedure. This procedure threads a catheter into the heart to record the heart's own electrical impulses and to assess the response to pacing and extra beats. Other tests such as cardiac stress tests are expensive and generally are performed in a hospital setting.

Traditional tests leave large numbers of patients with recurrent, unexplained, undiagnosed cardiac problems after undergoing these tests. The primary reasons these tests fall short are: 1) They only monitor the heart for a relatively limited amount of time, or 2) They require the patient to wear a device in their daily living that is embarrassing and inconvenient to wear, and/or that requires them to perform a task after experiencing a symptom. Therefore, there is a need for a diagnostic tool that allows one to continuously monitor the heart's rhythm and rate for long periods of time, on the order of several months or more, and requires no action by the patient at the time of fainting.

While a number of technologies have been developed to allow for patient monitoring at home or on the go, each of these technologies suffer from one or more major drawbacks. U.S. Pat. No. 5,458,124 to Stanko et al. describes an electrode and wireless transmitter system for use in measuring the physiological condition of a subject. The system in Stanko due to the rigidity of the system doesn't allow for good electrode contact with the patient's skin. Furthermore, the system in Stanko doesn't provide a good means for data error detection, nor in process adjustment by an external source. U.S. Pat. Nos. 5,862,803; 5,957,854; and 6,289,239 to Besson et al. provides for a wireless electrode system for measuring various body conditions. This system, however, is cumbersome, overly complex and limiting in that among other things it requires separate electronics for each electrode, as well as, a source of power external to the electrode. Because of the unique power requirements, this system

presumably doesn't allow for remote wireless monitoring at any great distance thereby creating an invisible tether to the receiver and limiting the versatility of the system.

The wireless technologies outlined above are interesting, but are not applicable for the easy measurement physiological signals and transmission over long periods of time. A compact, wireless physiological monitoring technology is needed for this purpose. It is therefore, an object of this invention to provide an electrode patch and wireless system for such a purpose. It is a further object of this invention to provide an electrode patch and wireless system with a feasible battery system. It is still a further object of this invention to provide an electrode patch and wireless system that allows for good measurement from two or more electrodes. It is still further an object of this invention to provide an electrode patch and wireless system that provided for data error correction. It is still further an object of this invention to provide an electrode patch and wireless system, which utilizes dry physiological electrodes for detecting the physiological signals.

SUMMARY OF THE INVENTION

The present invention is related, in general, to an electrode patch and/or a wireless system for measuring the physiological condition of a subject, and more particularly to an electrode patch for ECG monitoring. The present invention further includes a method of sensing, analyzing and/or transmitting or relaying a physiological signal.

The wireless system and/or electrode patch of the present invention is preferably lightweight and compact. The electrode patch preferably additionally provides a low, power system for extended battery life and use. The electrode patch and wireless system of the present invention still further preferably allows for good and reliable measurement of physiological signals form the subject. The electrode patch is still preferably simple to apply as a single patch, but versatile enough to be reconfigured as more than one patch.

In one embodiment, the present invention includes an electrode patch for sensing a physiological signal from a subject, the electrode patch comprising a base having an upper and a lower surface, the lower surface of the base comprising at least two electrodes for placing on a subjects skin and for sensing of a physiological signal from the subject; one or more electronic components for receiving the physiological signal and transmitting a signal corresponding to the physiological signal to a receiving unit or remote communication station, the one or more electronic components being attached to the base; and at least two electrical pathways connecting the at least two electrodes to the one or more electronic components which are not used as a primary means to mechanically attach the one or more electronic components to the base.

In another embodiment, the present invention includes an electrode patch for sensing a physiological signal from a subject, the electrode patch comprising a base having an upper and a lower surface, the lower surface of the base comprising at least two electrodes for placing on a subjects skin and for sensing of a physiological signal from the subject; one or more electronic components for receiving the physiological signal and transmitting a signal corresponding to the physiological signal to a receiving unit or remote communication station, the one or more electronic components; at least two electrical pathways connecting to the at least two electrodes; and a fastener for attaching the one or more electronic components to the base and electrically connecting the at least two electrical pathways to the one or more electronic components.

In still another embodiment, the present invention includes an electrode patch for sensing a physiological signal from a subject, the electrode patch comprising a base having an upper and a lower surface, the lower surface of the base comprising at least two electrodes for placing on a subjects skin and for sensing of a physiological signal from the subject; and one or more electronic components for receiving the physiological signal from the at least two electrodes, transmitting a signal corresponding to the physiological signal to a receiving unit or remote communication station, and receiving a signal from a remote transmitter, the one or more electronic components being attached to the base.

In still another embodiment, the present invention includes a wireless system for monitoring at least one physiological condition of a subject, the system comprising an electrode patch comprising a base having an upper and a lower surface, the lower surface of the base comprising at least two electrodes for placing on a subjects skin and for sensing of a physiological signal from the subject; and one or more electronic components for receiving the physiological signal, transmitting a signal corresponding to the physiological signal to a receiving unit or remote communication station and receiving a signal from a remote transmitter, the one or more electronic components being attached to the base; and a receiving unit or remote communication station for receiving, re-transmitting and/or processing the signal corresponding to the physiological signal, the receiving unit or remote communication station comprising a computer, processor and/or one or more electronic parts.

In yet another embodiment, the present invention includes a method comprising the steps of sensing and analyzing a physiological signal comprising the steps of measuring a physiological signal from a subject; transmitting wirelessly the physiological signal from the subject to a remote communication station; and transmitting data formed in part from the physiological signal from the remote communication station wirelessly or via the internet to another computer or processor system.

In still yet another embodiment, the present invention includes a method comprising the steps of applying a wireless electrode patch to a subject; digitizing and/or analyzing a physiological signal measured from the subject with the electrode patch; transmitting wirelessly from the electrode patch the digitized and/or analyzed physiological signal from the subject to a remote communication station; and re-transmitting a signal based in part from the physiological signal from the remote communication station wirelessly or via the internet to another monitor, computer or processor system.

Additional features and advantages of the invention will be set forth in the detailed description which follows, and in part will be readily apparent to those skilled in the art from that description or recognized by practicing the invention as described herein, including the detailed description which follows, the claims, as well as the appended drawings.

It is to be understood that both the foregoing general description and the following detailed description are merely exemplary of the invention, and are intended to provide an overview or framework for understanding the nature and character of the invention as it is claimed. The accompanying drawings are included to provide a further understanding of the invention, and are incorporated in and constitute a part of this specification. The drawings illustrate various embodi-

ments of the invention, and together with the description serve to explain the principles and operation of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1**. Plan cross-sectional view of the base of one embodiment of an electrode patch.

FIG. **2**. Plan cross-sectional view of the base of another embodiment of an electrode patch.

FIG. **3**. Plan cross-sectional view of an electrode patch utilizing base from FIG. **1**.

FIG. **4**. Exploded view of base laminate from FIG. **2**.

FIG. **5**. A), B), and C) are plan cross-sectional views of three embodiments of the reconfigurable electrical pathways of an electrode patches.

FIG. **6**. Plan cross-sectional view of another embodiment of a reconfigurable electrode of the present invention.

FIG. **7**. Plan cross-sectional view of another embodiment of the base of an electrode patch.

FIG. **8**. Plan cross-sectional view of one embodiment of a connector used with base laminate described in FIGS. **2** and **4**.

FIG. **9**. Schematic representation of one embodiment of a wireless monitoring system of the present invention.

FIG. **10**. Flow diagram of one embodiment of the one or more electronic components for the various devices and systems of the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The present invention is related, in general, to an electrode patch and/or a wireless system for measuring the physiological condition of a subject, and more particularly to an electrode patch for ECG monitoring. The present invention further includes a method of sensing and analyzing a physiological signal.

The electrode patch and the wireless system of the present invention are preferably used for sensing or detecting a physiological signal from a subject. The subject from which a physiological signal is measured being a human or other form of animal. The electrode patch and the wireless system of the present invention can be used in a variety of applications including but not limited to electrocardiography (ECG), electroencephalography (EEG), electrical impedance tomography (EIT), electromyography (EMG), and electro-oculography (EOG). Preferably, the electrode patch and the wireless system of the present invention is used for electrocardiography (ECG).

The electrode patch, which is a part of the wireless system of the present invention comprises a base having an upper and lower surface. The lower surface of the base comprising at least two electrodes. The electrodes are used for sensing a physiological signal from a subject. The electrode patch further comprises one or more electronic components. The one or more electronic components are used to receive the physiological signal from the at least two electrodes. The one or more electronic components also transmit or store a signal corresponding to the physiological signal to a remote receiving unit. Preferably, the one or more electronic components can further receive signals from one or more remote, receiving units. In a number of embodiments, the electrode patch further comprises at least two electrical pathways connecting to the at least two electrodes to one or more electronic components for receiving the physiological signal.

The electrical pathways are preferably attached to the base. More preferably, the electrical pathways are a line of conductive ink, which is printed on the upper surface of the base. Even more preferably, the electrical pathways are printed on the upper surface of the base and are drawn to a connector. This allows for separate production of the electronic components of the electrode patch and further for reuse or recycling of the electronic components. Also preferably, any of the electronic components and their electrical connections can be printed on the base of the electrode patch. The electrical pathways of the present invention are preferably greater than about 0.25 inches in length, more preferably greater than about 0.5 inches in length, and most preferably greater than about 1.0 inches in length. Preferably, the electrical pathways are made from some conductive ink or coating material.

The subject(s) referred to in the present invention can be any form of animal. Preferably the subject(s) are mammal, and most preferably human. The base having an upper and a lower surface can be made from any materials known to those skilled in the art. Preferably the base is made from a material which has the mechanical features necessary for the at least two electrodes and for attaching to the one or more electronic components. More preferably, the base is a laminate. Even more preferably, the base incorporates some type of foamed or cellular material that allows a certain flexibility and depth necessary for wells or depressions to hold conductive electrode gels or pastes. Preferably, the base comprises a flexible spacer layer with a modulus of elasticity of less than about 500,000 psi, more preferably less than about 100,000 psi, and most preferably less than about 30,000 psi. The spacer layer can be made from any polymer known to those skilled in the art. Preferably, the spacer layer is a foam or celled structure. Most preferably, the spacer layer is a closed cell structure, which doesn't allow for absorption of biological contaminants. Preferably the spacer layer of the base is between about 0.001 to about 0.3 inches thick, more preferably between about 0.01 to about 0.2 inches thick, and most preferably between about 0.03 to about 0.15 inches thick. If an adhesive is used to attach the electrode patch to the subject, preferably the adhesive is biologically compatible to the subject. More preferably, a pressure sensitive adhesive is used. Even more preferably, a removable pressure sensitive adhesive is used. The adhesives used include but are not limited to for example natural rubber, butyl, styrenic block copolymer, SBR, acrylics, and silicone based adhesives. Preferably, if a base laminate is used, the base laminate comprises a more rigid upper surface wherein the upper surface has an elastic modulus greater than that of the spacer layer. This allows for a better surface on which to attach the one or more electronic components of various embodiments of the present invention.

The lower surface of the base, preferably, comprises at least two electrodes, more preferably more than at least three electrodes, and most preferably more than at least four electrodes. The at least two electrodes can be any type of electrode known to those skilled in the art for sensing a physiological signal. Preferably, the at least two electrodes of the present invention can be conventional electrodes known to those skilled in the art comprising a sensing element and a conductive gel for transmitting the signal between the subjects skin and the sensing element; or dry electrodes comprising a penetrator for detecting physiological signals below the surface of the skin as a sensing element. Dry physiological recording electrodes of the type described in U.S. patent application Ser. No. 09/949,055 are herein incorporated by reference. Dry electrodes provide the

advantage that there is no gel to dry out, no skin to abrade or clean, and that the electrode can be applied in hairy areas such as on an animal or on a male human's chest. Alternatively, the subject(s) skin may be mechanically abraded, or an amplified electrode may be used. Preferably, the at least two electrodes are one signal electrode and one reference electrode. The at least two electrodes don't have to be of the same type, i.e., for example one could be a conductive gel electrode and the other a dry electrode. The at least two electrodes can be any shape known to be useful to those skilled in the art. For example the electrodes can be circular or non-circular in shape. Preferably, the at least two electrodes are in close proximity with no more than 9 inches between each of their sensing elements or their closest sensing elements, more preferably with no more than 6 inches between each of their sensing elements or their closest sensing elements, and most preferably with no more than 3 inches between each of their sensing elements or their closest sensing elements.

The electrode patch is attached to the subject by any method or means known to those skilled in the art. By way of example but not limitation, the electrode patch may be attached to the subject by adhesive on the lower surface of the base, by adhesive on the electrodes on the lower surface of the base, by an elastomeric band that is attached to the based and about the subject, or some combination thereof.

The electrode patch further comprises one or more electronic components for detecting the physiological signal from the at least two electrodes. While some of the electronic components such as the battery or antenna may be separate from the other electronic components, and in the case of the antenna may be printed right onto the base. One or more of the electronic components are mechanically attached to the base. Preferably, the one or more electronic components are mechanically attached to the upper surface of the base. The one or more electronic components can be attached by any means known to those skilled in the art including but not limited to hooks, hangers, Velcro, clips and the like. The one or more electronic components are, however, preferably not attached to the base by the electrical pathways. If, however, this is not possible preferably the one or more electronic components are attached with a connecter that incorporates at least two electrical pathways.

The one or more electronic components for detecting the physiological signal from the at least two electrodes is a wireless device, which most preferably transmits the physiological signals to a remote receiving unit. Preferably, the one or more electronic components also filter (and possibly amplify) the detected signal, and more preferably convert this detected physiological signal, which is in an analog form into a digital signal for transmission to the remote receiving unit. The one or more electronic components are attached to the subject as part of the electrode patch. Further preferably, the one or more electronic components can receive a signal from the remote receiving unit or other remote transmitters. The one or more electronic components may include circuitry for but are not limited to for example electrode amplifiers, signal filters, analog to digital converter, RF output antenna, RF input antenna, RF output/input antenna, subcarrier VCO, transmitter VCO, tuning crystal, phase-locked loop, frequency select switches, a DC power source and combinations thereof. The one or more electronic components may comprise one processing chip, multiple chips, single function components or combinations thereof, which can perform all of the necessary functions of detecting the physiological signal from the electrode, transmitting a signal corresponding to the physiological signal to a receiving unit and optionally receiving a signal from a remote transmitter. These one or more electronic components can be assembled on a printed circuit board or by any other means known to those skilled in the art. Preferably, the one or more electronic components can be assembled on a printed circuit board or by other means so its imprint covers an area less than 4 in^2, more preferably less than 2 in^2, even more preferably less than 1 in^2, still even more preferably less than 0.5 in^2, and most preferably less than 0.25 in^2.

Preferably, the circuitry of the one or more electronic components is appropriately modified so as to function with any suitable miniature DC power source. More preferably, the DC power source is a battery. A preferred battery of the present invention are zinc-air hearing aid batteries. Zinc-air hearing aid batteries offer a high energy density and nearly constant output voltage during discharge, which is preferable. Preferably, a three-cell stack of zinc-air batteries are used, each cell offering a steady 1.2 V, and producing a stable and reliable 3.6 V. The most preferred battery of the present invention are Lithium-ion batteries. Lithium-ion batteries also offer a high energy density and nearly constant output voltage during discharge. Additionally, these commercially available batteries are readily available and inexpensive and a single battery produces slightly greater than 3 V, which is preferable. Alternatively, high frequency energy may be transmitted to the electrode patch from some external source to power the circuitry of the one or more electronic components through some type of capacitor.

Preferably, the circuitry of the one or more electronic components comprises data acquisition circuitry further including an electrode amplifier which detects the physiological signal from the at least two electrodes and integrates the detected physiological signals into a single signal and amplifies it to some power level. The data acquisition circuitry is designed with the goal of reducing size, lowering (or filtering) the noise, increasing the DC offset rejection and reducing the system's offset voltages. The data acquisition circuitry may be constrained by the requirements for extremely high input impedance, very low noise and rejection of very large DC offset and common-mode voltages, while measuring a very small signal of interest. Additional constraints arise from the need for a "brick-wall" style input protection against ESD and EMI. The exact parameters of the design, such as input impedance, gain and passband, can be adjusted at the time of manufacture to suit a specific application via a table of component values to achieve a specific full-scale range and passband.

More preferably, a low-noise, lower power instrumentation amplifier is used. The inputs for this circuitry is guarded with preferably, external ESD/EMI protection, and very high-impedance passive filters to reject DC common-mode and normal-mode voltages. Still preferably, the instrumentation amplifier gain can be adjusted from unity to approximately 100 to suit the requirements of a specific application. If additional gain is required, it preferably is provided in a second-order antialias filter, whose cutoff frequency can be adjusted to suit a specific application, with due regard to the sampling rate. Still preferably, the reference input of the instrumentation amplifier is tightly controlled by a DC cancellation integrator servo that uses closed-loop control to cancel all DC offsets in the components in the analog signal chain to within a few analog-to digital converter (ADC) counts of perfection, to ensure long term stability of the zero reference.

Preferably, the physiological signal is converted to a digital form. This can be achieved with an electronic component or processing chip through the use of an ADC. More

preferably, the ADC restricts resolution to 12-bits due to the ambient noise environment in such chips. Despite this constraint, the ADC remains the preferable method of choice for size-constrained applications such as with the present invention unless a custom data acquisition chip is used because the integration reduces the total chip count and significantly reduces the number of interconnects required on the printed circuit board.

Preferably, the circuitry of the one or more electronic components comprises a digital section. Part of this circuitry may include one or more chips preconfigured to perform some or all of the digital processing for use with existing wireless protocols including but not limited to wireless local area networks (IEEE 802.11 including WiFi), wireless personal area networks (IEEE 802.15 including Bluetooth and ZigBee), wireless metropolitan area networks (IEEE 802.16) or others known to those skilled in the art. More preferably, the heart of the digital section is the MicroChip™ PIC 16LC771 microcontroller or other comparable microcontrollers including microcontrollers from competing companies including Atmel and Texas Instruments. The preferable MicroChip™ PIC 16LC771 microcontroller or other comparable microcontroller would contain sufficient data and program memory, as well as peripherals, which allow the entire digital section as well as the ADCs to be neatly bundled into a single carefully programmed processing chip. Still preferably, the onboard counter/timer sections are used to produce the data acquisition timer, and can further be used to measure the VCO frequency and to confirm synthesizer lock. Still preferably, an onboard synchronous serial (SPI) port is used to control the synthesizer, to generate a RF data stream, and to communicate with external test equipment. Also preferably, an onboard main oscillator generates not only the microcontroller clock, but also the reference clock for the synthesizer. Additional digital outputs are used to control specific functions. Still preferably, one ADC input is dedicated to measurement of the VCO tune voltage to allow for automation of the final testing, and a separate function multiplexed onto this same pin allows limited direct control of the VCO tune voltage during automated final testing.

The synthesizer can induce distortion in the transmitted digital data when the data does not contain exactly equal numbers of ones and zeroes over a prolonged interval. This distortion arises because the synthesizer sees the modulation as error to be servoed out, and fights the modulation as it attempts to steer the VCO back to the nominal frequency. Preferably, the reference oscillator has the ability to modulate the reference frequency with any low-frequency content of the final transmitted digital data, with one of the results being that the reference and the VCO move in concert during modulation and therefore do not distort the data, and the low-frequency content of the designed data packet format should result in only minimal distortion. Optionally, this capability can be removed to reduce the imprint of the printed circuit board holding the one or more electronic components.

Preferably, the circuitry for the one or more electronic components is designed to provide for communication with external quality control test equipment prior to sale, and more preferably with automated final test equipment. In order to supply such capability without impacting the final size of the finished unit, one embodiment is to design a communications interface on a separate PCB using the SPI bus with an external UART and level-conversion circuitry to implement a standard RS-232 interface for connection to a personal computer or some other form of test equipment. The physical connection to such a device requires significant PCB area, so preferably the physical connection is designed to keep the PCB at minimal imprint area. More preferably, the physical connection is designed with a break-off tab with fingers that mate with an edge connector. This allows all required final testing and calibration of the electrode patch, including the programming of the processing chip memory, can be carried out through this connector, with test signals being applied to the analog inputs through the normal connections which remain accessible in the final unit. By using an edge fingers on the production unit, and an edge connector in the production testing and calibration adapter, the electrode patch can be tested and calibrated without leaving any unnecessary electronic components or too large a PCB imprint area on the final unit.

Preferably, the circuitry for the one or more electronic components comprises nonvolatile, rewriteable memory. Alternatively, if the circuitry for the one or more electronic components doesn't comprise nonvolatile, rewriteable memory then an approach should be used to allow for reprogramming of the final parameters such as radio channelization and data acquisition and scaling. Without nonvolatile, rewriteable memory, the program memory can be programmed only once. Therefore one embodiment of the present invention involves selective programming of a specific area of the program memory without programming the entire memory in one operation. Preferably, this is accomplished by setting aside a specific area of program memory large enough to store several copies of the required parameters. Procedurally, this is accomplished by initially programming the circuitry for the one or more electronic components with default parameters appropriate for the testing and calibration of the electrode patch. When the final parameters have been determined, the next area is programmed with these parameters. If the final testing and calibration reveals problems, or some other need arises to change the values, additional variations of the parameters may be programmed. The firmware of various embodiments of the present invention scans for the first blank configuration block and then uses the value from the preceding block as the operational parameters. This arrangement allows for reprogramming of the parameters up to several dozen times, with no size penalty for external EEPROM or other nonvolatile RAM. The circuitry for the one or more electronic components has provisions for in-circuit programming and verification of the program memory, and this is supported by the break-off test connector. The operational parameters can thus be changed up until the time at which the test connector is broken off just before shipping the final unit. Thus the manufacturability and size of the circuitry for the one or more electronic components is optimized.

Preferably the circuitry of the one or more electronic components includes an RF transmitter. Still preferably includes a custom voltage controlled oscillator (VCO) made up of discrete electronic components, and a phase-locked loop (PPL) synthesizer built around commercially available electronic components. Still preferably, the whole radio section of the circuitry can be powered down independently of the digital section components. Still further preferably, the synthesizer is controlled by the firmware via the SPI bus, and uses a crystal oscillator to derive a precision clock.

In these embodiments, the VCO design is unique in several ways. A buffer is preferably required between the core VCO active element and the antenna, to minimize pulling of the VCO frequency by physical movement at or near the antenna. Still preferably, the VCO itself uses a negative-resistance oscillator configuration. Still preferably,

this is a stacked configuration to allow sharing between the VCO and the buffer. Still preferably, this configuration allows for two or more different configurations of the buffer with negligible size impact on the imprint of the circuitry of the one or more electronic components. In one configuration, the VCO and buffer are in a cascade configuration (common base amplifier), such that the buffer provides voltage gain and buffering. In another configuration, the configuration becomes a common-emitter buffer, with the potential to allow firmware control of the transmitted power during PLL lock by reducing the gain of the buffer during lock. Preferably, this capability is provided with no size or power impact in the common-emitter configuration and reduces the potential for interference with other units during unit startup. On the other hand, the cascade configuration preferably is more resistant to antenna pulling, so precharge of the tune voltage and careful sequencing and timing of the startup are required to prevent interference.

Preferably, tuning of the VCO is performed by using a unique architecture that minimizes power consumption while significantly reducing noise compared to more conventional approaches such as using a varactor to perform tuning in response to an applied voltage. Preferably, in various embodiments of the present invention, the PLL applies a tuning voltage to the top side of a varactor, reversing biasing of the varactor to the level required to achieve a desired oscillation frequency. Conventional designs mix the modulation with this tune voltage to modulate the carrier produced by the VCO. However, this mixing normally requires a summing junction plus a buffer, and the buffer generates significant 1/F noise, seriously degrading the phase noise performance of the VCO. In addition, the required swing of the modulation voltage is orders of magnitude smaller than that of the tune voltage. Preferably in various embodiments of the present invention, only the PLL tune voltage is injected at the top of the varactor, and the modulation voltage is injected at the bottom of the varactor. By pre-inverting the modulation voltage, a bias voltage is achieved across the varactor that is the arithmetic sum of the tune voltage and the modulation voltage without the undesirable interactions of the conventional approaches. Because the required swing of the modulation voltage is very small, a resistive divider can be used as the last step in applying the modulation voltage, thus keeping the signal amplitude very large right up until the final division, forcing any accompanying noise to also be divided down before application to the varactor. This enhances the signal-to-noise ratio in the modulation voltage. Additionally because the required swing is very small, the division ratio in the final divider is large, allowing for very low current draw while still providing extremely low Thevenin equivalent resistance and very low thermal noise at this sensitive node.

Another feature of the circuitry of the one or more electronic components preferably is an antenna. The antenna, preferably, is designed onto the upper surface of the base of the electrode patch and is integrated in the rest of the circuitry. The antenna can be configured in a number of ways, for example as a single loop, dipole, dipole with termination impedance, lagarithmic-periodic, dielectric, strip conduction, patch or reflector antenna. The antenna is designed to include but not be limited to the best combination of usable range, production efficiency and end-system usability. Preferably, the antenna consists of one or more conductive wires or strips, which are arranged in a pattern to maximize surface area. The large surface area will allow for lower transmission outputs for the data transmission. The large surface area will also be helpful in receiving high frequency energy from an external power source for storage. Optionally, the radio transmissions of the present invention may use frequency-selective antennas for separating the transmission and receiving bands, if a RF transmitter and receiver are used on the electrode patch, and polarization-sensitive antennas in connection with directional transmission. Polarization-sensitive antennas consist of, for example, thin metal strips arranged in parallel on an insulating carrier material. Such a structure is insensitive to or permeable to electromagnetic waves with vertical polarization; waves with parallel polarization are reflected or absorbed depending on the design. It is possible to obtain in this way, for example good cross polarization decoupling in connection with linear polarization. It is further possible to integrate the antenna into the frame of a processing chip or into one or more of the other electronic components, whereby the antenna is preferably realized by means of thin film technology. The antenna can serve to just transfer electrode patch data or for both transferring data to and for receiving control data received from a remote communication station which can include but is not limited to a wireless relay, a computer or a processor system. Optionally, the antenna can also serve to receive high-frequency energy (for energy supply or supplement). In any scenario, only one antenna is required for transmitting data, receiving data and optionally receiving energy. Optionally, directional couples can be arranged on the transmitter outputs of the electrode patch and/or the remote communication station. The couplers being used to measure the radiated or reflected radio wave transmission output. Any damage to the antenna (or also any faulty adaptation) thus can be registered, because it is expressed by increased reflection values.

An additional feature of the present invention is an optional identification unit. By allocating identification codes—a patient code (for each electrode patch), the remote communication station is capable of receiving and transmitting data to several subjects, and for evaluating the data if the remote communication station is capable of doing so. This is realized in a way such that the identification unit has a control logic, as well as a memory for storing the identification codes. The identification unit of the electrode patch is preferably programmed by radio transmission of the control characters and of the respective identification code from the programming unit of the remote communication station to the electrode patch. More preferably, the electrode patch comprises switches in the electrode patch as programming lockouts, particularly for preventing unintentional reprogramming of the electrode patch.

In any RF link, errors are an unfortunate and unavoidable problem. Analog systems can often tolerate a certain level of error. Digital systems, however, while being inherently much more resistant to errors, also suffer a much greater impact when errors occur. Thus the present invention when used as a digital system, preferably includes an error control subarchitecture. Preferably, the RF link of the present invention is digital. RF links can be one-way or two-way. One-way links are used to just transmit data. Two-way links are used for both sending and receiving data.

If the RF link is one-way error control, then this is preferably accomplished at two distinct levels, above and beyond the effort to establish a reliable radio link to minimize errors from the beginning. At the first level, there is the redundancy in the transmitted data. This redundancy is performed by adding extra data that can be used at the remote communication station or at some station to detect and correct any errors that occurred during transit across the airwaves. This mechanism known as Forward Error Correc-

tion (FEC) because the errors are corrected actively as the signal continues forward through the chain, rather than by going back to the transmitter and asking for retransmission. FEC systems include but are not limited to Hamming Code, Reed-Solomon and Golay codes. Preferably, a Hamming Code scheme is used. While the Hamming Code scheme is sometimes maligned as being outdated and underpowered, the implementation in certain embodiments of the present invention provides considerable robustness and extremely low computation and power burden for the error correction mechanism. FEC alone is sufficient to ensure that the vast majority of the data is transferred correctly across the radio link. Certain parts of the packet must be received correctly for the receiver to even begin accepting the packet, and the error correction mechanism in the remote communication station reports various signal quality parameters including the number of bit errors which are being corrected, so suspicious data packets can be readily identified and removed from the data stream.

Preferably, at a second, optional level, an additional line of defense is provided by residual error detection through the use of a cyclic redundancy check (CRC). The algorithm for this error detection is similar to that used for many years in disk drives, tape drives, and even deep-space communications, and is implemented by highly optimized firmware within the electrode patch processing circuitry. During transmission, the CRC is first applied to a data packet, and then the FEC data is added covering the data packet and CRC as well. During reception, the FEC data is first used to apply corrections to the data and/or CRC as needed, and the CRC is checked against the message. If no errors occurred, or the FEC mechanism was able to properly correct such errors as did occur, the CRC will check correctly against the message and the data will be accepted. If the data contains residual errors (which can only occur if the FEC mechanism was overwhelmed by the number of errors), the CRC will not match the packet and the data will be rejected. Because the radio link in this implementation is strictly one-way, rejected data is simply lost and there is no possibility of retransmission.

More preferably, the RF link utilizes a two-way (bi-directional) data transmission. By using a two-way data transmission the data safety is significantly increased. By transmitting redundant information in the data emitted by the electrodes, the remote communication station is capable of recognizing errors and request a renewed transmission of the data. In the presence of excessive transmission problems such as, for example transmission over excessively great distances, or due to obstacles absorbing the signals, the remote communication station is capable of controlling the data transmission, or to manipulate on its own the data emitted by the electrode patch. With control of data transmission it is also possible to control or re-set the parameters of the electrode patch, e.g., changing the transmission channel. This would be applicable for example if the signal transmitted by the electrode patch is superimposed by other sources of interference then by changing the channel the remote communication station could secure a flawless and interference free transmission. Another example would be if the signal transmitted by the electrode patch is too weak, the remote communication station can transmit a command to the electrode patch increasing its transmitting power. Still another example would be the remote communication station causing the electrode patch to change the data format for the transmission, e.g., in order to increase the redundant information in the data flow. Increased redundancy allows transmission errors to be detected and corrected more easily. In this way, safe data transmissions are possible even with the poorest transmission qualities. This technique opens in a simple way the possibility of reducing the transmission power requirements of the electrode patch. This also reduces the energy requirements of the electrode patch, thereby providing longer battery life. Another advantage of a two-way, bi-directional digital data transmission lies in the possibility of transmitting test codes in order to filter out external interferences such as, for example, refraction or scatter from the transmission current. In this way, it is possible to reconstruct falsely transmitted data. Due to the safe and effective one-way and two-way transmission of the various embodiments of the present invention between the electrode patch and the remote communication station, the present invention is particularly suitable for use at home or work, such as for example monitoring infants or heart patients, especially where no technical personnel are available.

The remote communication station of various embodiments of the present invention can be any device known to receive RF transmissions used by those skilled in the art to receive transmissions of physiological data from the electrode patch. The remote communication station by way of example but not limitation can include a communications device for relaying the transmission, a communications device for re-processing the transmission, a communications device for re-processing the transmission then relaying it to another remote communication station, a computer with wireless capabilities, a PDA with wireless capabilities, a processor, a processor with display capabilities, and combinations of these devices. Optionally, the remote communication station can further transmit data both to another device and/or back to the electrode patch. Further optionally, two different remote communication stations can be used, one for receiving transmitted physiological data from the electrode patch and another for sending data to the electrode patch. For example, with the wireless physiological monitoring system of the present invention, the remote communication system of the present invention can be a wireless router, which establishes a broadband internet connection with the electrode patch and transmits the physiological signal to a remote internet site for analysis, preferably by the subject's physician. Another example is where the remote communication system is a PDA, computer or cell phone, which receives the physiological data transmission from the electrode patch, optionally re-processes the information, and re-transmits the information via cell towers, land phone lines or cable to a remote site for analysis. Another example is where the remote communication system is a computer or processor, which receives the physiological data transmission from the electrode patch and displays the data or records it on some recording medium, which can be displayed or transferred for analysis at a later time.

Preferably, the wireless monitoring system of the present invention can be used to notify a doctor, monitoring service or an emergency medical dispatch team of a problem with the subject. To provide for the maximum flexibility of the subject preferably, the subject can be monitored by application of a wireless electrode patch to the subject. Preferably, the electrode patch provides electronics and a battery such that the battery or patch only need to be changed no more than 1 time a day, more preferably no more than once every two days, and most preferably no more than once every four days. The wireless electrode patch then digitizes and/or analyzing a physiological signal measured from the subject with the electrode patch. This digitized or analyzed physiological signal is then transmitting wirelessly from the

electrode patch to a remote communication station. This remote communication station allows the subject wide movement. Preferably, the remote communication station can pick up and transmit signals from distances of greater than about 5 feet from the subject, more preferably greater than about 10 feet from the subject, even more preferably greater than about 20 feet from the subject, still even more preferably greater than about 50 feet from the subject, still even more preferably greater than about 200 feet from the subject, and most preferably greater than about 500 feet from the subject. The remote communication station is used to re-transmit the signal based in part from the physiological signal from the remote communication station wirelessly or via the internet to another monitor, computer or processor system. This allows the physician or monitoring service to review the subjects physiological signals and if necessary to make a determination, which could include dispatching help.

Referring now to the drawings, FIG. **1** is a planar cross-sectional view of the base of an electrode patch. In FIG. **1**, the electrode patch **10** comprises a base **12** having an upper **13** and lower surface (not shown). The base **12** comprises at least two electrodes **14** for placing on a subject's skin and for sensing a physiological signal from the subject. The at least two electrodes **14** can either be attached to the lower surface of the base **12**, be incorporated into the lower surface of the base **12**, or be formed into the base **12** itself. If the electrodes **14** are formed into the base itself then preferably the base **12** is a laminate. If the base **12** is a laminate then preferably the base **12** comprises a lower surface consisting of an adhesive layer, at least one spacer layer and an upper surface **13**. The base is preferably multiple layers, and most preferably is a laminate. The electrode patch **10** in FIG. **1** consists of four electrodes **14**—with one of those electrodes being used as a reference electrode **15**. The electrode patch **10** also comprises at least one electrical pathway **20**, the at least one electrical pathway for connecting the electrode **14** to a connector **18** or one or more electronic components (not shown) for transmitting the physiological signal detected by the electrodes **14** to a remote communication station (not shown). In addition to the electrical pathways **20**, optionally the electrodes **14** may include other types of connectors such as the button type connector **16** or other mechanical connectors **16**. This embodiment of the electrode patch **10** further comprises a mechanical weak-point **22** built into the base **12** to allow for separation of one of the electrodes **14** from the base **12**.

FIG. **2** is a plan cross-sectional view of another embodiment of the base laminate used in the electrode patch of the present invention. In FIG. **2**, the base laminate **12** comprises an upper **13** and a lower surface (not shown). The base **12** comprises at least two electrodes **14** for placing on a subject's skin and for sensing a physiological signal from the subject. The at least two electrodes **14** can either be attached to the lower surface of the base **12**, be incorporated into the lower surface of the base **12**, or be formed into the base **12** itself. If the electrodes **14** are formed into the base itself then preferably the base **12** is a laminate. If the base **12** is a laminate then preferably the base **12** comprises a lower surface consisting of an adhesive layer, at least one spacer layer and an upper surface **13**. The base is preferably multiple layers, and most preferably is a laminate. The base laminate **12** in FIG. **2** consists of four electrodes **14**—with one of those electrodes being used as a reference electrode **15**. The base laminate **12** also comprises at least one electrical pathway **20**, the at least one electrical pathway for connecting the electrode **14** to a connector (not shown) or one or more electronic components (not shown) for transmitting the physiological signal detected by the electrodes **14** to a remote communication station (not shown). The base laminate **12** further contains two flexible arms **17** which allow for versatility in placement of the electrode patch **10** and for use with varying size subjects. This embodiment of the base laminate **12** provides for a connector (not shown) which snaps or connects over a spring portion **21** of the laminate. The spring portion further comprises electrical contacts **19** which connect the electrode patch **10** electrical components (not shown) with preferably the base laminate. The electrical components being housed in the connector.

FIG. **3** is a planar cross-sectional view an electrode patch. In addition to the features disclosed in FIG. **1** for the base, the embodiment of the electrode patch **10** shown in FIG. **3** includes one or more electronic components **34** further including a battery **32** and a single loop antenna **30**.

FIG. **4**. is an exploded view of the base laminate from FIG. **2**. The base laminate **12** in this embodiment used for an electrode patch comprises an adhesive layer (not shown) a bottom layer **23** with a bottom surface **28**, spacer layer **24**, and a top layer **25** with an upper surface (not shown). The layers forming the base laminate can be any materials known to those skilled in the art. Preferably, the materials are those approved by the FDA for these types of applications. For this particular embodiment, preferably the bottom layer **23** is an adhesive formed from a removable/releasable type pressure sensitive adhesive. The space layer **24** is preferably formed from a low modulus polyurethane or some other thermoplastic material selected for its ability to be laminated, soft texture for patient comfort and suitability for other aspects of the particular applications of the present invention. Attached to the lower surface of the bottom layer **23** or disposed within the spacer layer **24** are at least two electrodes **14**. The electrodes **14** in this particular embodiment are pre-gelled and incorporate a hypo-allergenic, silver/silver-chloride gel. The electrodes **14** are formed onto the top layer **25** with the bottom layer **23** and spacer layer **24** providing a well to hold the silver/silver chloride gel.

FIGS. **5** A), B), and C) are planar cross-sectional views of three embodiments of the reconfigurable electrical pathways of the electrode patches of the present invention. FIG. **5** A) is an electrode portion **14** of the base **12** of an electrode patch (not shown). The electrode **14** in this embodiment having both a mechanical connection **16** providing a potential electrical pathway, and an electrical pathway **20** wherein the electrical pathway **20** connects the electrode **14** to a connector (not shown) or directly to the electronic components (not shown) of the electrode patch. A mechanical weak-point **22** further being incorporated into the base to allow for separation of the electrode **14** from the base, and in this particular embodiment, breaks or disconnects the electrical pathway **20** connecting the electrode **14** to the connector or electronic components. FIG. **5** B) is another embodiment of an electrode portion **14** of the base **12** of an electrode patch. In this embodiment, the mechanical weak-point **22** allows the electrical pathway **20** connecting the electrode **14** to the connector or electronic components to be broken or disconnected, without separating the electrode **14** from the base **12**. FIG. **5** C) is another embodiment of an electrode portion **14** of the base laminate **12** of an electrode patch. In this embodiment, there is an additional electrical pathway **20** such as an antenna or connecting to another electrode wherein the mechanical weak-point **22** allows this electrical pathway to be broken or disconnected.

FIG. **6** is a plan cross-sectional view of another embodiment of a reconfigurable electrode of the base of the electrode patch. In this embodiment, there are first and second

electrodes, each electrode **14** being connected by an electrical pathway **20** to a connector **18** there being further one or more mechanical weak-points built into the base **12** wherein a certain portion of the base **12** can be separated without breaking either electrical pathway **20**. In this particular embodiment one of the electrical pathways **20** is permanently affixed or connected to the base **12** after a certain electrical pathway connection point **26**, but rather is a coiled or looped wire, which will enable the second electrode to be moved a distance from the first electrode after separation from the base allowing for different configurations of the electrode patch (not shown).

FIG. **7** is a plan cross-sectional view of another embodiment of the base of an electrode patch. In addition to the features disclosed and described in FIG. **1** for the base, the embodiment of the electrode patch **10** shown in FIG. **6** includes an additional electrical pathway **36**, which can be broken or disconnected by tearing or separating the base at one of the mechanical weak points **22** and hence the configuration change can be detected by the electronics attached to connector **18**.

FIG. **8** is a plan cross-sectional view of one embodiment of a connector, which is embedded into the housing for one or more electronic components, and can be used with a base laminate such as described in FIGS. **2** and **4**. The housing **88** with the embedded connector region **86** provides a locking mechanism **84** for holding the spring portion **21** of the base laminate **12**. The connector region **86** further provides one or more electrical contact pads, which connect the electrical components (not shown) in the housing **88** with the electrical contacts **19** of the base laminate **12**. The connector region **86** in this embodiment uses electrical contact pads **80** to make such connection.

FIG. **9** is a schematic representation of one embodiment of the wireless monitoring system of the present invention. In FIG. **9**, the subject **40** has an electrode patch **10** placed upon his or her chest **42**, and attached by adhesive or other means, in order to monitor the physiological electrical signals from the subject's heart. The electrode patch **10** is one embodiment of the present invention described elsewhere in this application. The electrode patch **10** comprises a base **12** having an upper **13** and lower (not shown) surface and includes at least two electrodes (not shown) for placing on the subject's **40** skin. The electrode patch **10** further comprising one or more electronic components **34** including in this embodiment a battery **32**. The one or more electronic components for receiving a physiological signal from the electrodes placed on the subject and for transmitting a signal corresponding to the physiological signal to a receiving unit **44**, or remote communications station or device. The corresponding signal being transferred preferably is via radio wave **48**. The receiving unit **44** being a PDA, cell phone or some other type of device that can relay and/or process the received signal and optionally transmit instructions back to the electrode patch **10**. In this embodiment the receiving unit **44** is a PDA which in turn is connected to a computer monitor **46** for processing the radio wave **48** signal and making decisions on whether to re-transmit the signal to another remote location such as a doctor's office or some other monitoring service, and whether to transmit a return signal to the one or more electronic components **34** of the electrode patch **10**.

FIG. **10** is a flow diagram for one embodiment of the one or more electronic components described for the present invention. In this flow diagram, the electrical pathways **20** carry an electrical signal from the electrodes to the electrical components. The electrode input **60** is then amplified with a signal amplifier **62** and digitized **63** for further processing with a computer or microprocessor **64**. The computer or microprocessor **64** contains local memory **66**. The processed physiological signal is passed to a radio transceiver **70** and broadcast via radio antenna **74** for further analysis or transmission. The electrical components are powered by a power supply **68** which can be either AC or DC and preferably is a battery.

It will be apparent to those skilled in the art that various modifications and variations can be made to the present invention without departing from the spirit and scope of the invention. Thus, it is intended that the present invention cover the modifications and variations of this invention provided they come within the scope of the appended claims and their equivalents.

What is claimed is:

1. An electrode patch for sensing all electrophysiological signal from a subject, the electrode patch comprising:

a base having an upper and a lower surface, the lower surface of the base comprising at least two electrodes for placing on a subjects skin and for sensing of an electrophysiological signal from the subject;

one or more electronic components for receiving the electrophysiological signal and transmitting a signal corresponding to the electrophysiological signal to a receiving unit or remote communication station, the one or more electronic components being mechanically attached to the base; a battery separate from the one or more electronic components for powering the one or more electronic components; and

at least two electrical pathways connecting the at least two electrodes to the one or more electronic components which are not used as a primary means to mechanically attach the one or more electronic components to the base.

2. The electrode patch in claim **1**, wherein the at least two electrodes are dry physiological recording electrodes each comprising at least one penetrator.

3. The electrode patch in claim **1**, wherein the one or more electronic components are capable of receiving a signal from a remote transmitter and the received signal in part is used by the one or more electronic components to control the transmitted signal from the one or more electronic components.

4. The electrode patch in claim **3**, wherein the base is a laminate of at least two layers.

5. The electrode patch in claim **4**, wherein the lower surface of the base further comprises a foam material with a well formed in the foam material for each of the at least two electrodes and each of the wells contains a conductive gel.

6. The electrode patch in claim **1**, wherein the electrophysiological signal is an EKG signal.

7. An electrode patch for sensing an electrophysiological signal from a subject, the electrode patch comprising:

a base having an upper and a lower surface, the lower surface of the base comprising at least two electrodes for placing on a subjects skin and for sensing of an electrophysiological signal from the subject;

one or more electronic components mechanically attached to the upper surface of the base for receiving the electrophysiological signal and transmitting a wireless radio frequency signal corresponding to the electrophysiological signal to a receiving unit or remote communication station; a battery for powering the one or more electronic components;

at least two electrical pathways connecting to the at least two electrodes; and

a connector for mechanically attaching the one or more electronic components to the upper surface of the base and electrically connecting the at least two electrical pathways to the one or more electronic components.

8. The electrode patch in claim **7**, wherein the at least two electrodes are dry physiological recording electrodes each comprising at least one penetrator.

9. The electrode patch in claim **7**, wherein the one or more electronic components are capable of receiving a wireless signal from a remote transmitter and the received signal in part is used by the one or more electronic components to control the transmitted wireless signal from the one or more electronic components.

10. The electrode patch in claim **9**, wherein the base is a laminate of at least two layers.

11. The electrode patch in claim **10**, wherein the lower surface of the base further comprises a foam material with a well formed in the foam material for each of the at least two electrodes and each of the wells contains a conductive gel.

12. The electrode patch in claim **7**, wherein the electrophysiological signal is an EKG signal.

13. A wireless system for monitoring at least one physiological condition of a subject, the system comprising:

an electrode patch comprising a base having an upper and a lower surface, the lower surface of the base comprising at least two electrodes for placing on a subjects skin and for sensing of an electrophysiological signal from the subject; and one or more electronic components for receiving the electrophysiological signal, transmitting a wireless signal corresponding to the electrophysiological signal to a receiving unit or remote communication station, and receiving a wireless signal from a remote transmitter, the one or more electronic components being mechanically attached to the upper surface of the base; and

and a receiving unit or remote communication station for receiving, re-transmitting and/or processing the wireless signal corresponding to the electrophysiological signal, the receiving unit or remote communication station comprising a computer, processor and/or one or more electronic parts.

14. The wireless system in claim **13**, further comprising a battery for powering the one or more electronic components.

15. The wireless system in claim **14**, wherein the at least two electrodes are dry physiological recording electrodes each comprising at least one penetrator.

16. The wireless system in claim **15**, wherein the remote computer or processor system is a personal data assistant (PDA).

17. The wireless system in claims **16**, wherein the lower surface of the base further comprises a foam material with a well formed in the foam material for each of the at least two electrodes and each of the wells contains a conductive gel.

18. The wireless system in claim **13**, wherein the electrophysiological signal is an EKG signal.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,206,630 B1
APPLICATION NO. : 10/879666
DATED : April 17, 2007
INVENTOR(S) : Matthew David Tarler

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 18,
Line 18, delete "all electrophysiological" and insert -- an electrophysiological --.

Signed and Sealed this

Fifteenth Day of September, 2009

David J. Kappos

David J. Kappos
Director of the United States Patent and Trademark Office

Exhibit B

US 20080139953A1

(19) **United States**

(12) **Patent Application Publication**

(10) **Pub. No.: US 2008/0139953 A1**

(43) **Pub. Date: Jun. 12, 2008**

Baker et al.

(54) **BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE**

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(21) Appl. No.: **11/591,619**

(22) Filed: **Nov. 1, 2006**

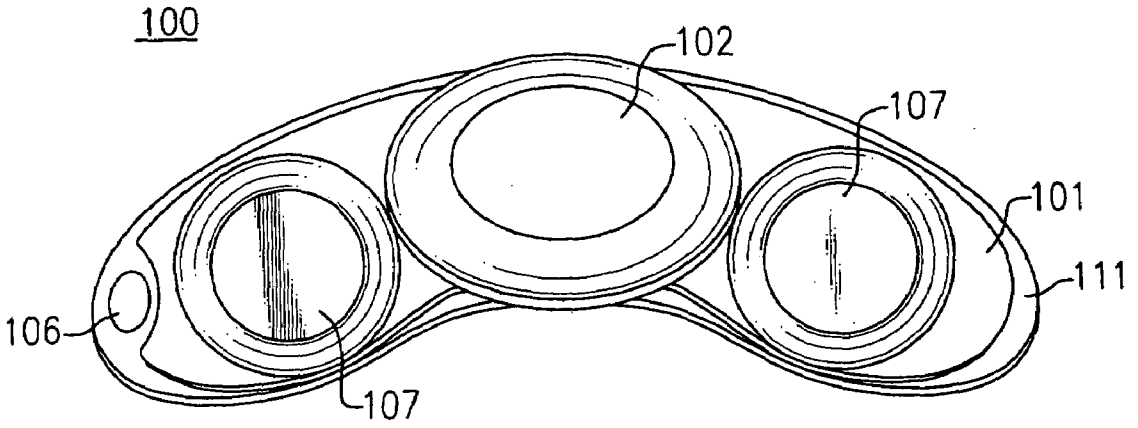
Publication Classification

(51) **Int. Cl.**
A61B 5/04 (2006.01)

(52) **U.S. Cl.** **600/509**

(57) **ABSTRACT**

A body worn patient monitoring device includes at least one disposable module including a plurality of electrical connections to the body. The body worn patient monitoring device also includes at least one communication-computation module, the communication-computation module having at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals. A radio circuit communicates a raw physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module. The body worn patient monitoring device, including the at least one disposable module and the at least one communication-computation module, is directly non-permanently affixed to the skin surface of the patient.



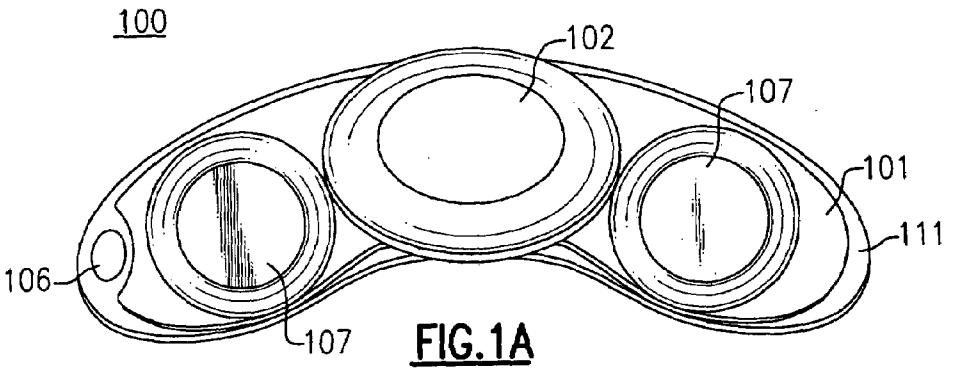


FIG.1A

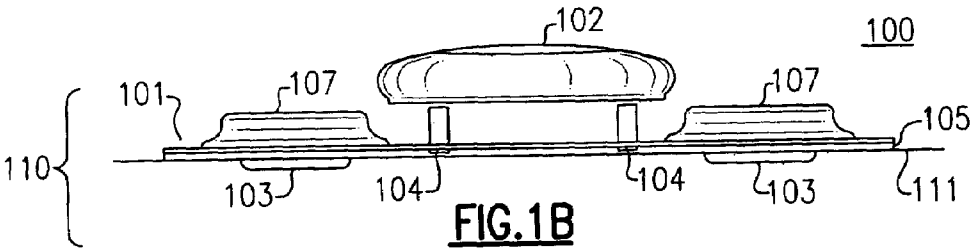


FIG.1B

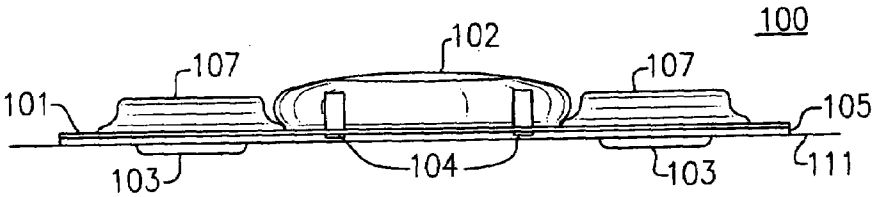


FIG.1C

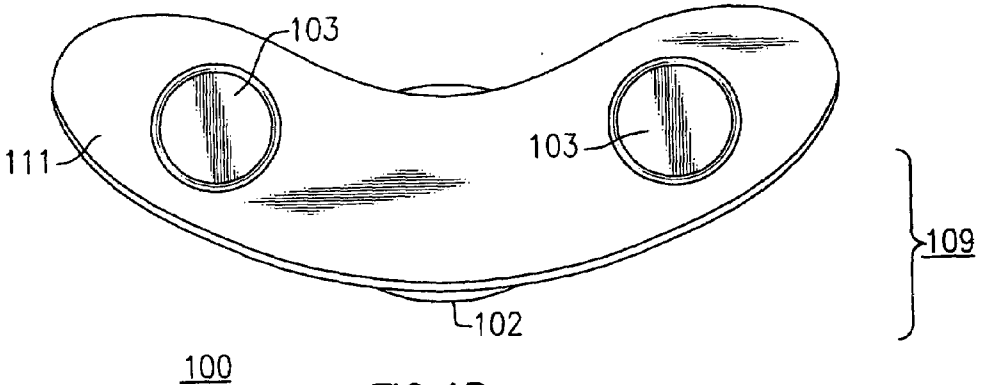


FIG.1D

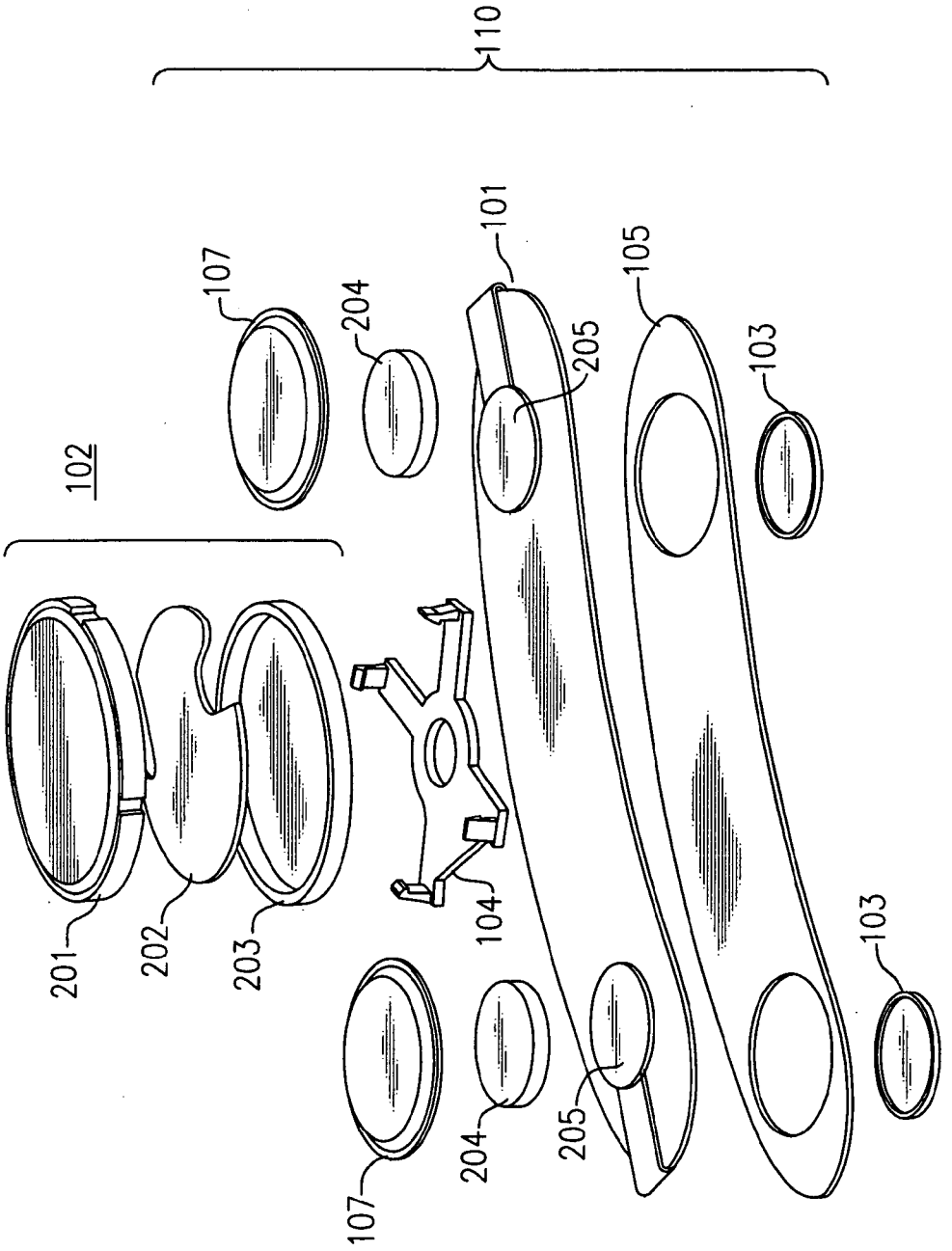


FIG.2

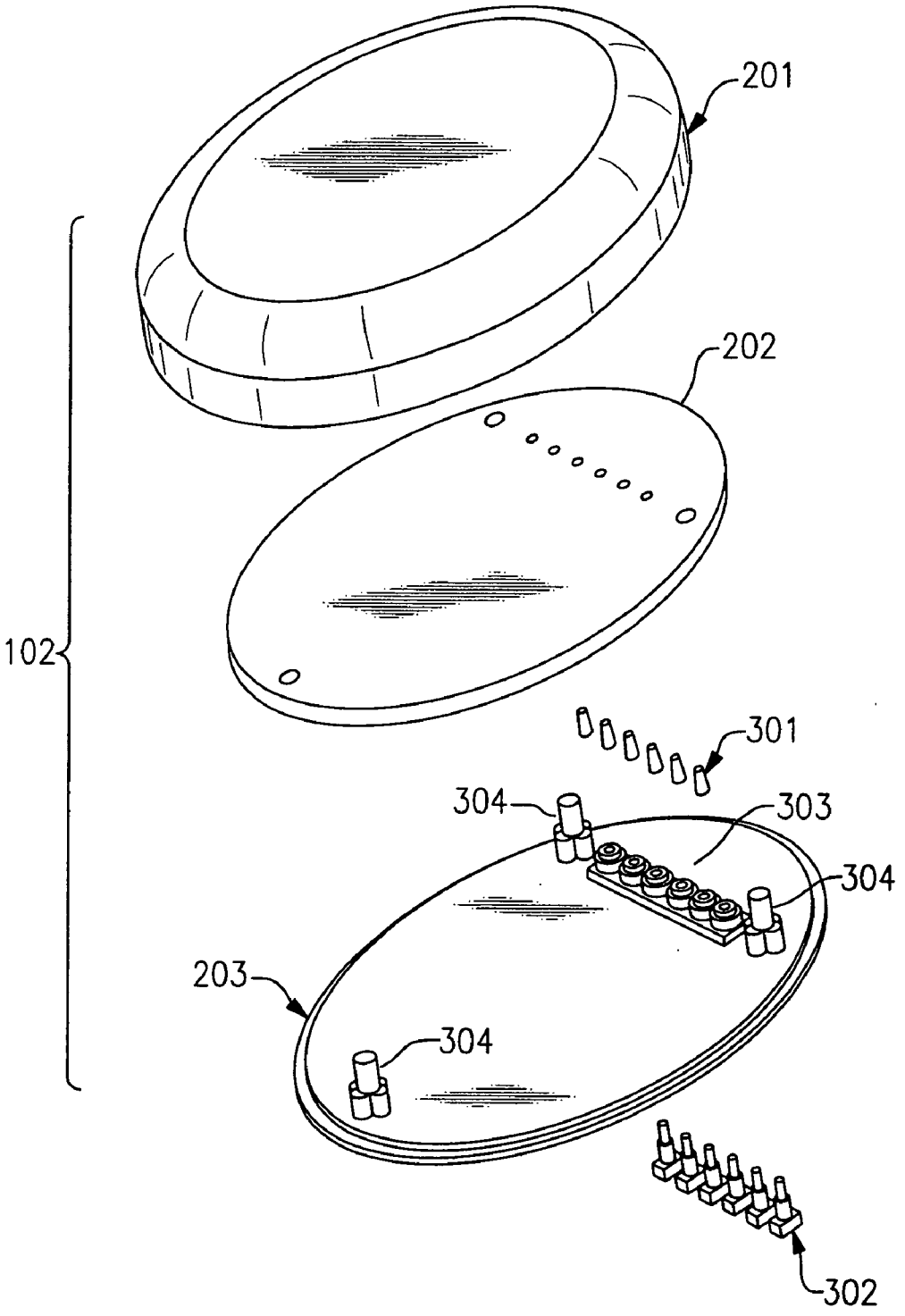


FIG.3

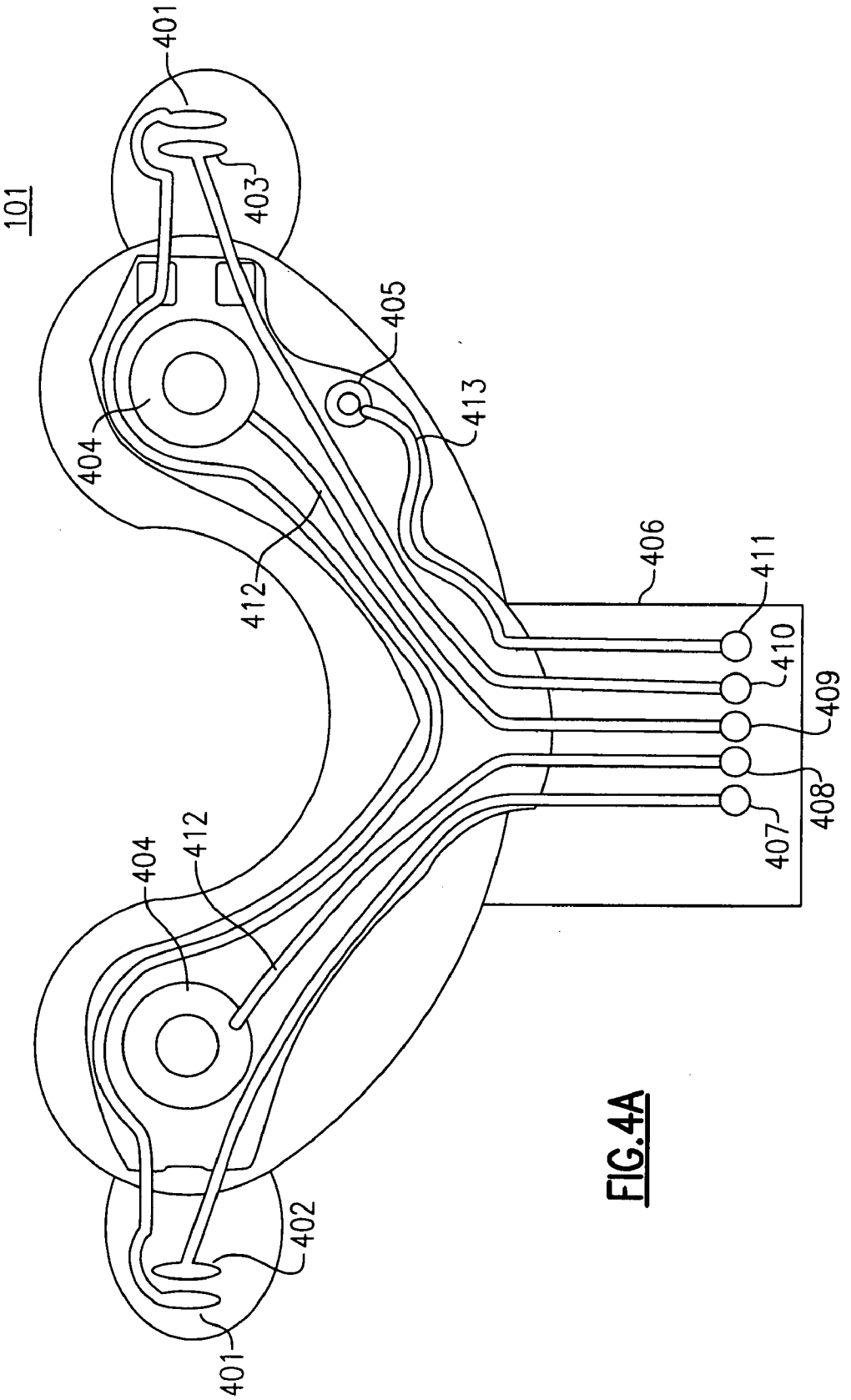

101
401
403
405
413
404
412
406
411
410
409
408
407
404
412
402
401

FIG.4A

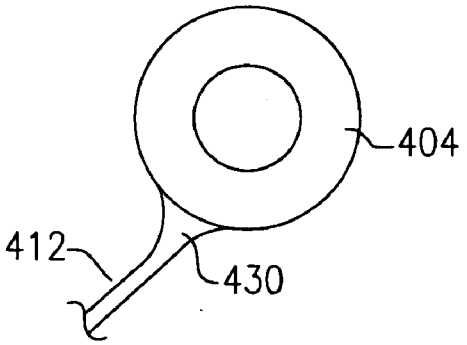


FIG.4B

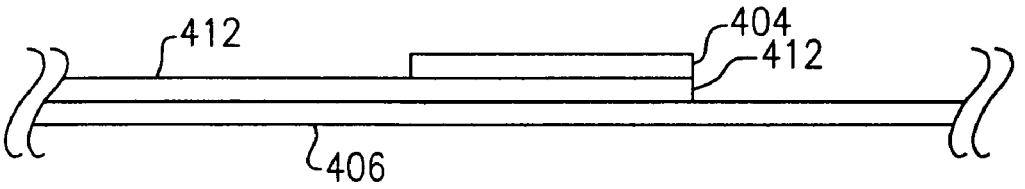


FIG.4C

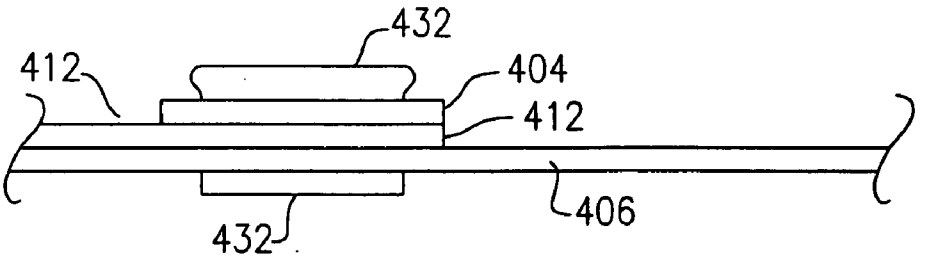


FIG.4D

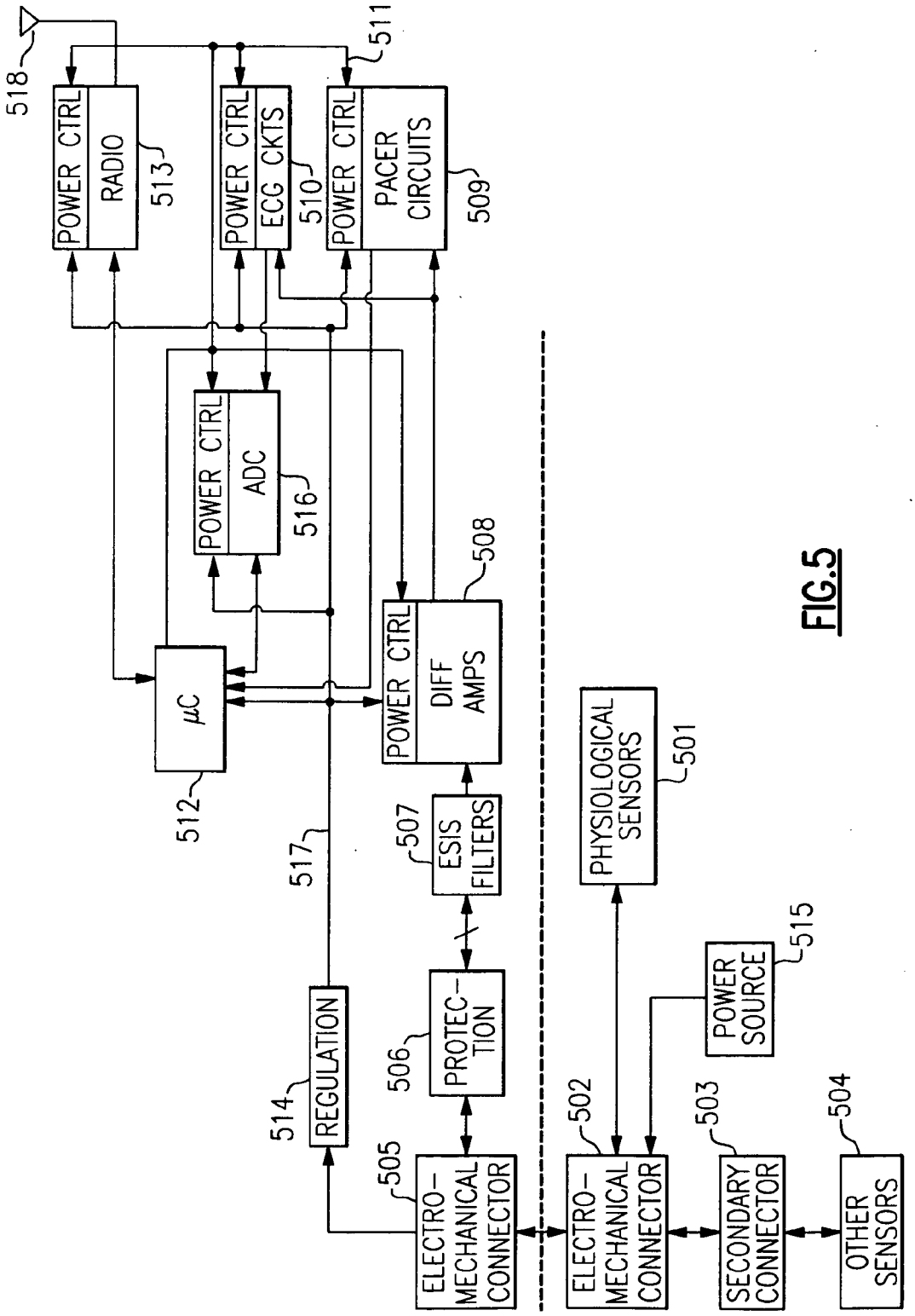

518
POWER CTRL
RADIO
513
POWER CTRL
ECG CKTS
510
511
POWER CTRL
PACER CIRCUITS
509
POWER CTRL
ADC
516
508
POWER CTRL
DIFF AMPS
µC
512
517
507
ESIS FILTERS
PHYSIOLOGICAL SENSORS
501
514
REGULATION
506
PROTEC-TION
POWER SOURCE
515
505
ELECTRO-MECHANICAL CONNECTOR
502
ELECTRO-MECHANICAL CONNECTOR
503
SECONDARY CONNECTOR
504
OTHER SENSORS

FIG.5

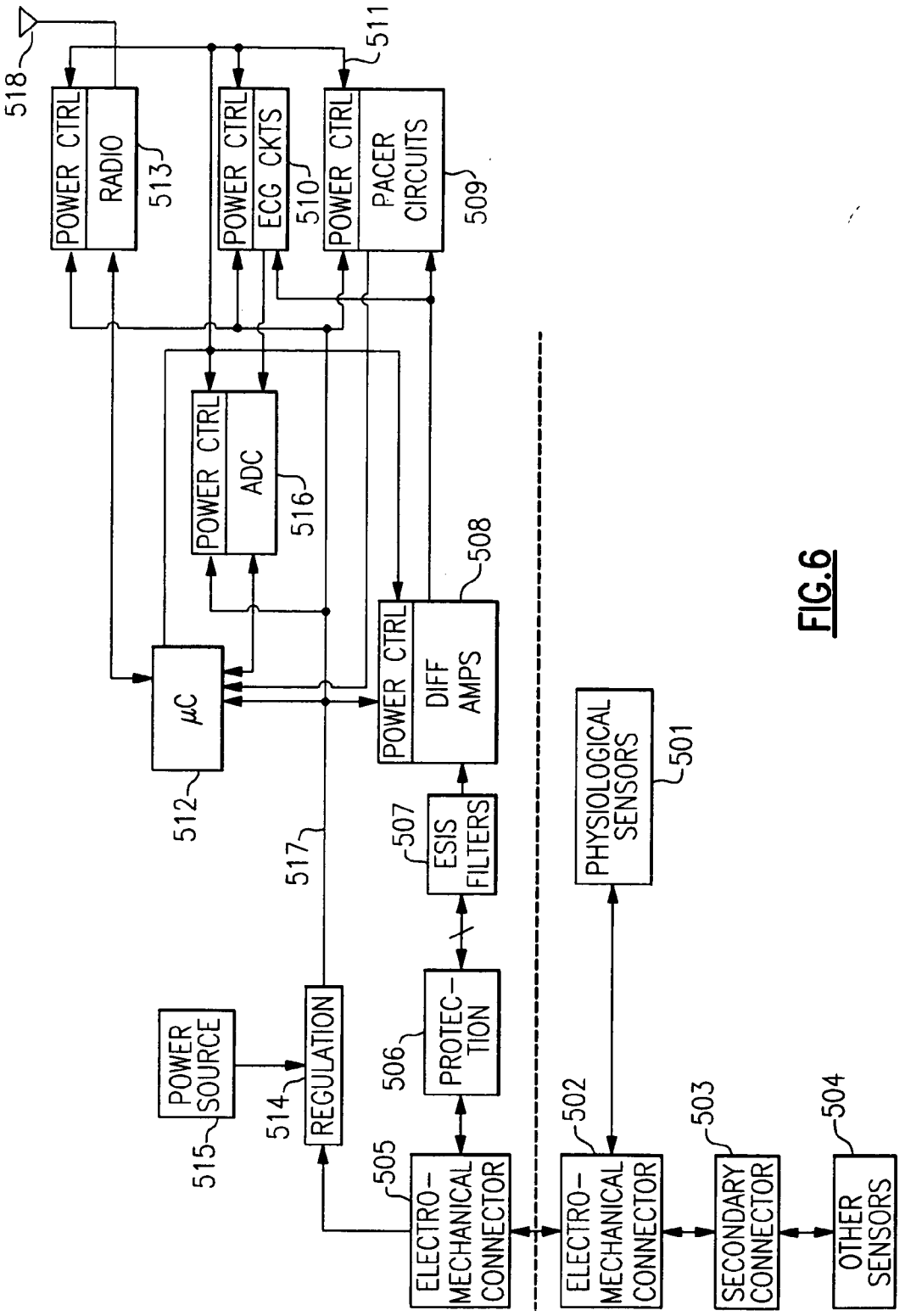

518
POWER CTRL
RADIO
513
POWER CTRL
ECG CKTS
510
511
POWER CTRL
PACER CIRCUITS
509
POWER CTRL
ADC
516
508
POWER CTRL
DIFF AMPS
µC
512
517
507
ESIS FILTERS
PHYSIOLOGICAL SENSORS
501
POWER SOURCE
515
514
REGULATION
506
PROTEC-TION
505
ELECTRO-MECHANICAL CONNECTOR
502
ELECTRO-MECHANICAL CONNECTOR
503
SECONDARY CONNECTOR
504
OTHER SENSORS

FIG.6

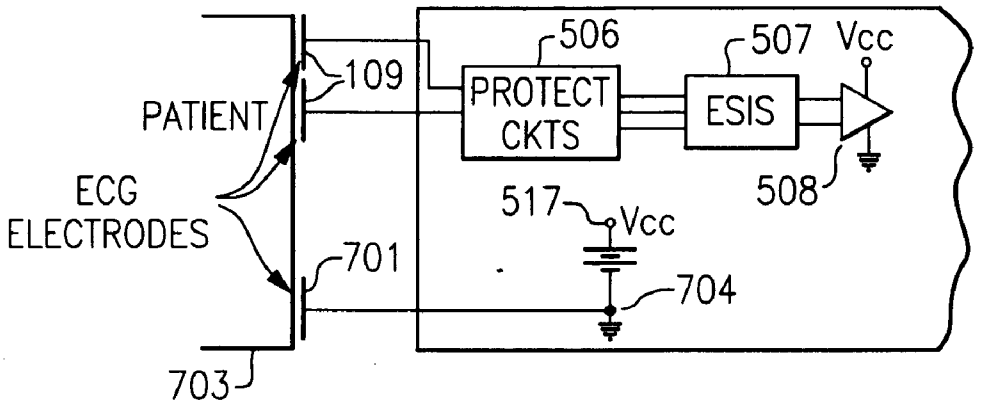

506
507
Vcc
109
PROTECT CKTS
ESIS
PATIENT
ECG ELECTRODES
508
517
Vcc
701
704
703

FIG.7A

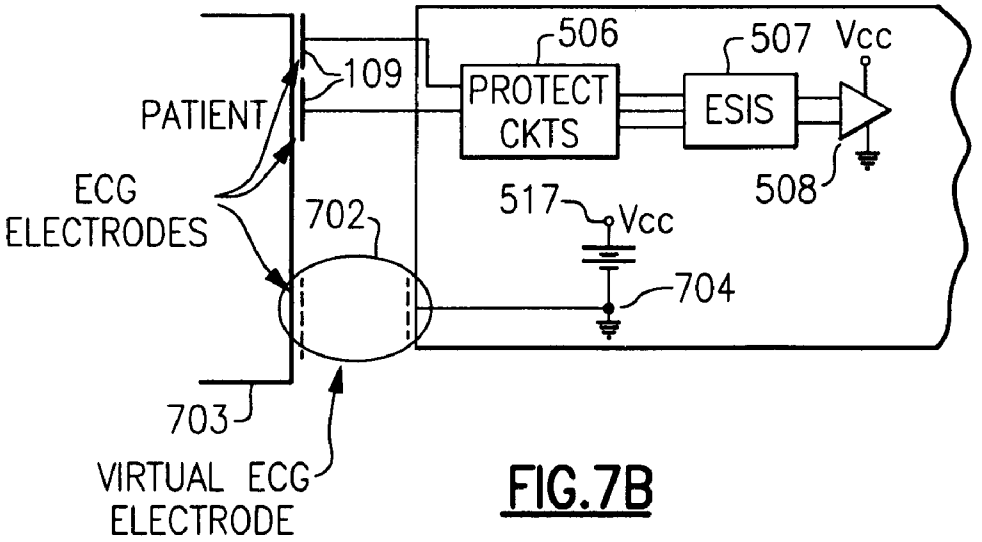

506
507
Vcc
109
PROTECT CKTS
ESIS
PATIENT
ECG ELECTRODES
508
517
Vcc
702
704
703
VIRTUAL ECG ELECTRODE

FIG.7B

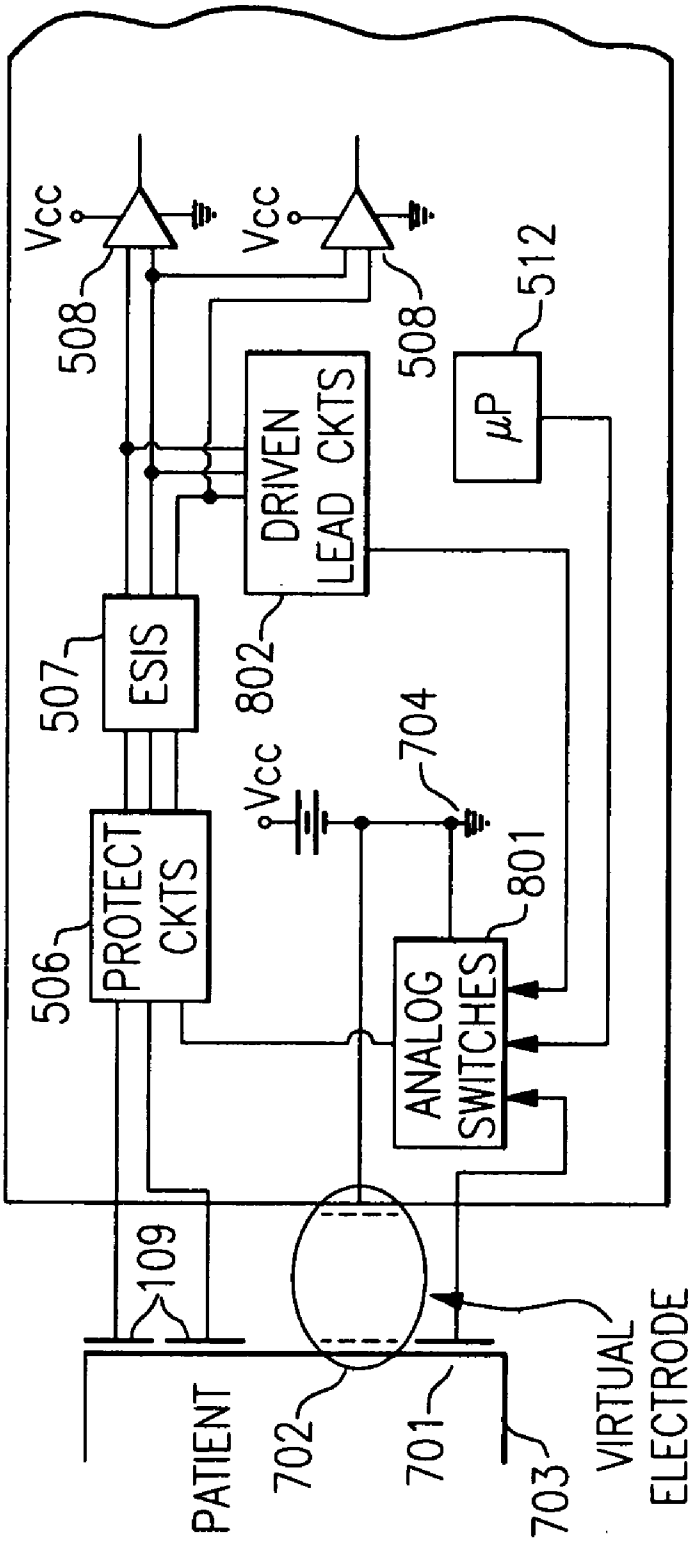

Vcc
Vcc
508
508
512
μP
DRIVEN LEAD CKTS
802
507
ESIS
704
Vcc
506
PROTECT CKTS
801
ANALOG SWITCHES
109
PATIENT
702
701
703
VIRTUAL ELECTRODE

FIG.8

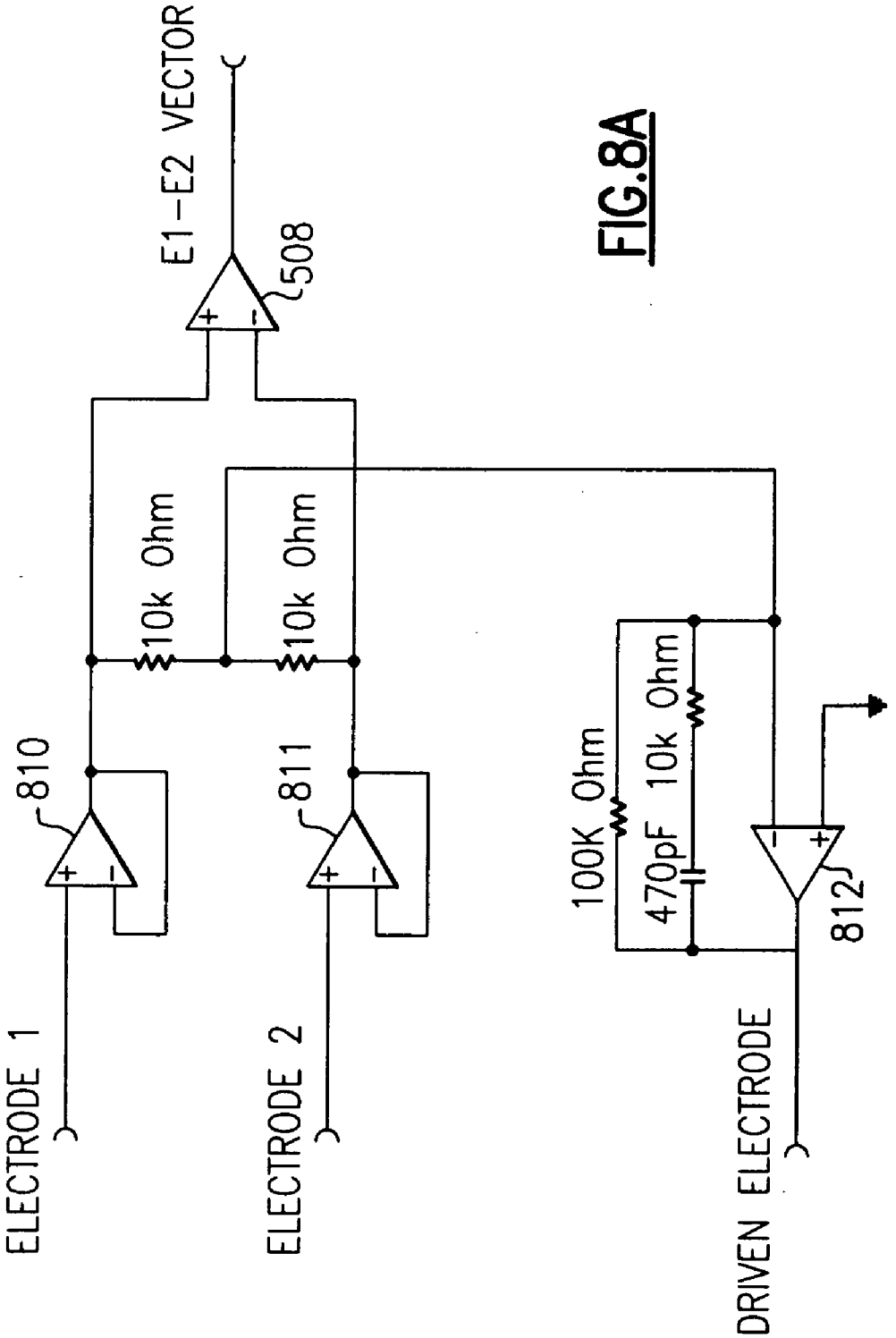

E1-E2 VECTOR
508
10k Ohm
10k Ohm
810
811
100K Ohm
470pF
10k Ohm
812
ELECTRODE 1
ELECTRODE 2
DRIVEN ELECTRODE

FIG.8A

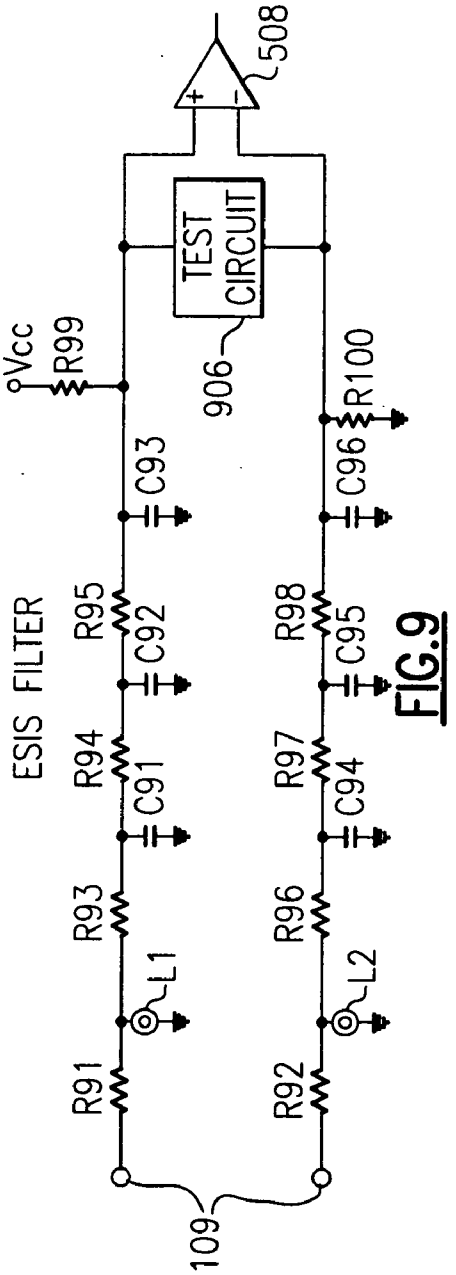

508
TEST CIRCUIT
906
Vcc
R99
R100
C93
C96
ESIS FILTER
R95
C92
R98
C95
R94
C91
R97
C94
R93
L1
R96
L2
R91
R92
109

FIG.9

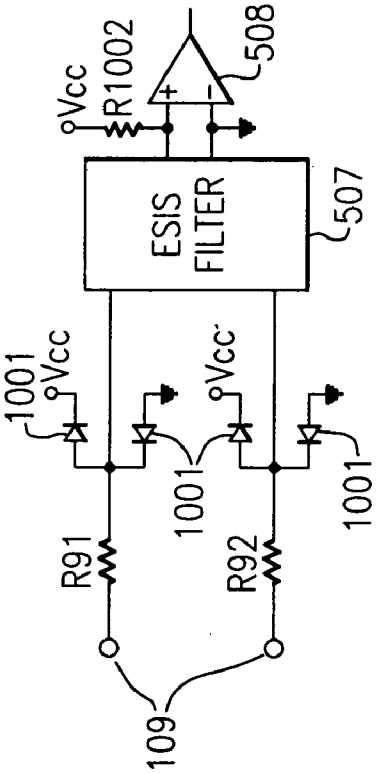

Vcc
R1002
508
ESIS FILTER
507
1001
Vcc
1001
Vcc
1001
R91
R92
109

FIG.10

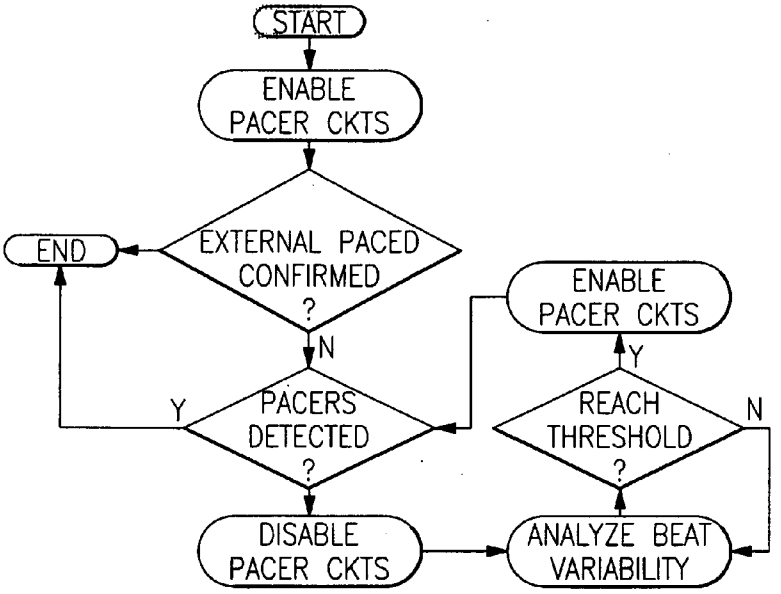


FIG.11

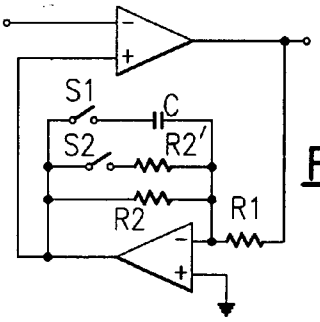


FIG.12

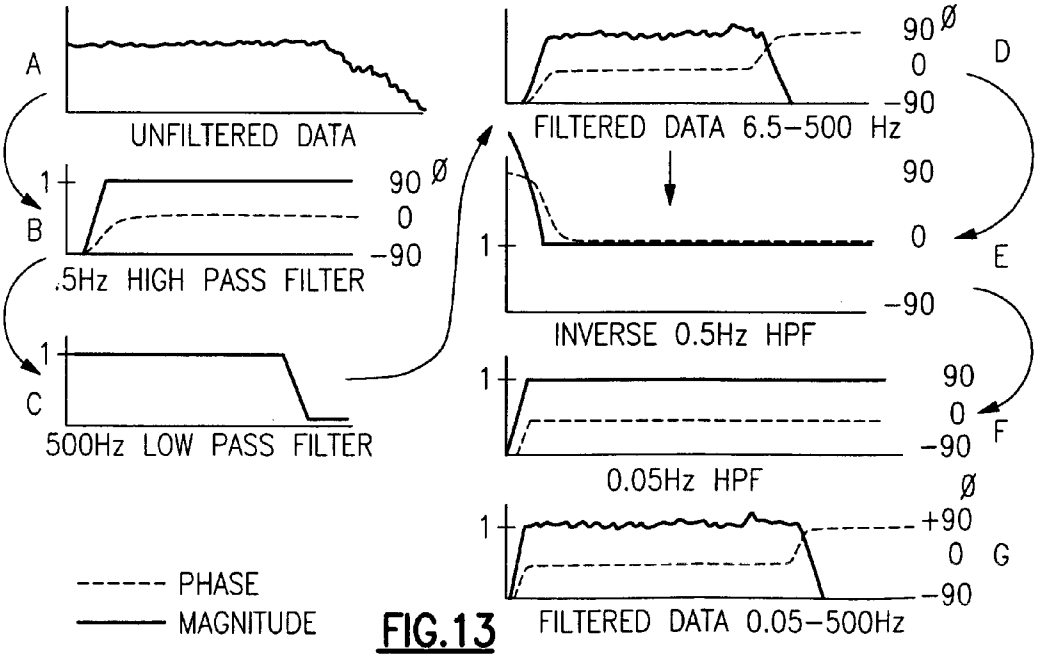


FIG.13

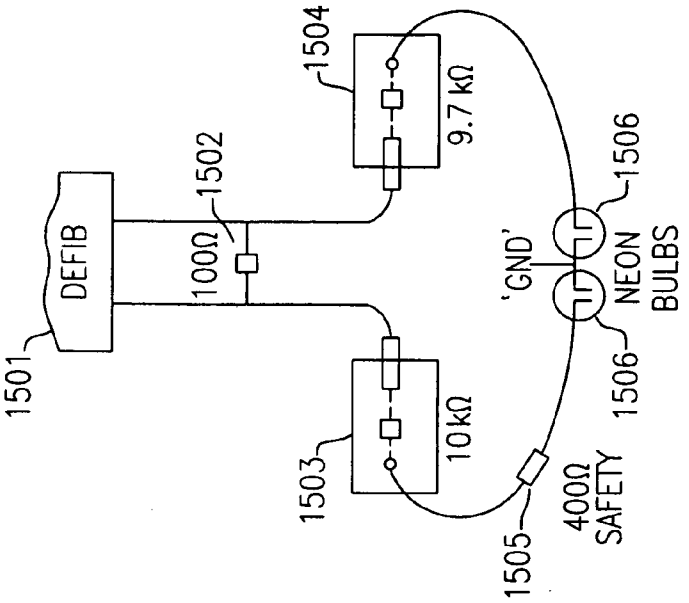

1504
9.7 kΩ
1502
1506
DEFIB
100Ω
'GND'
NEON
BULBS
1501
1506
1503
10kΩ
400Ω
SAFETY
1505

FIG.15

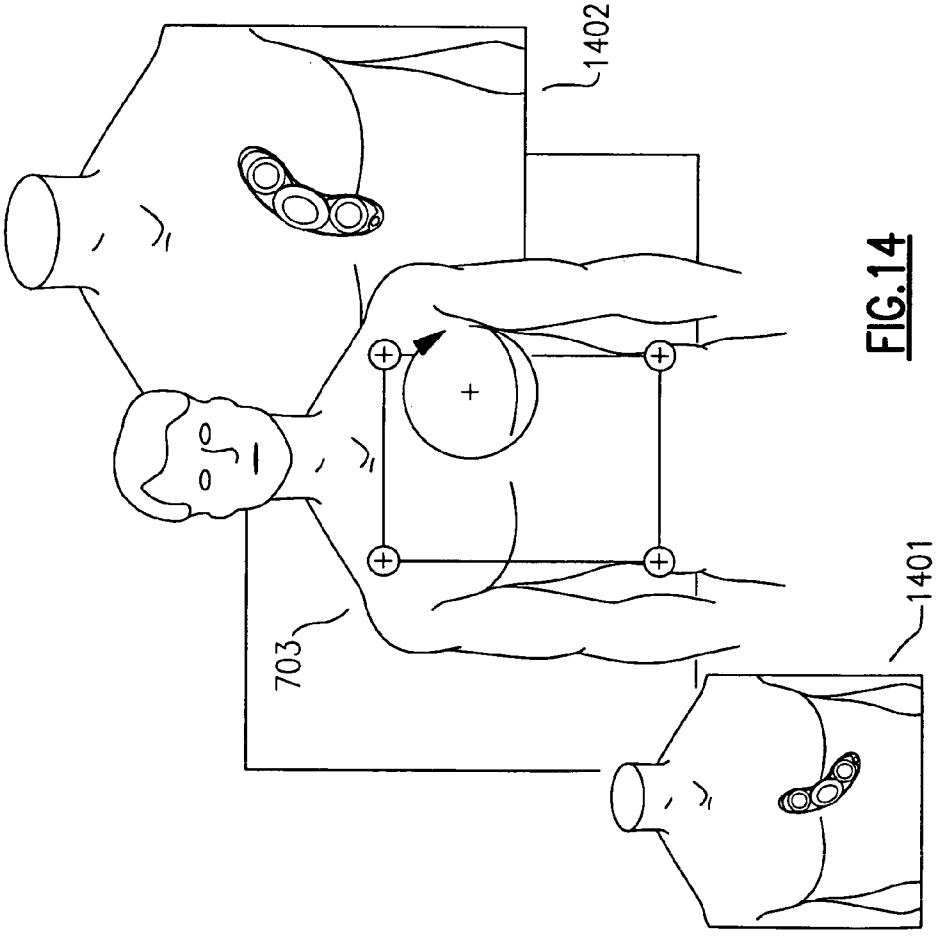

1402
703
1401

FIG.14

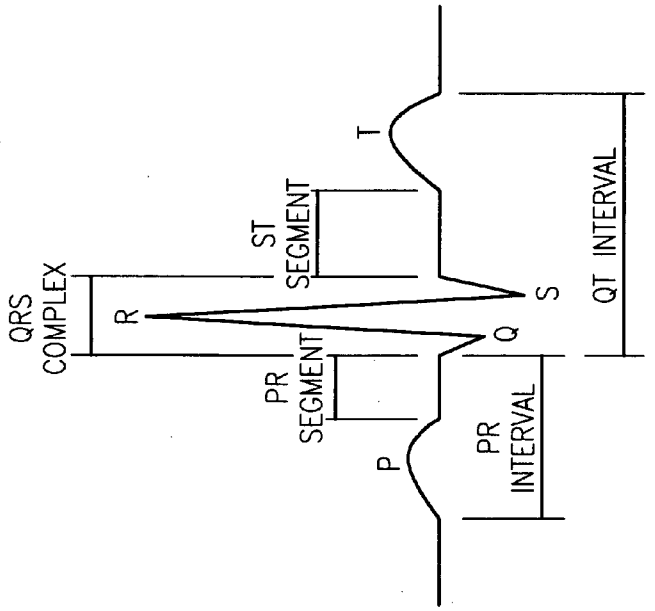


FIG.17

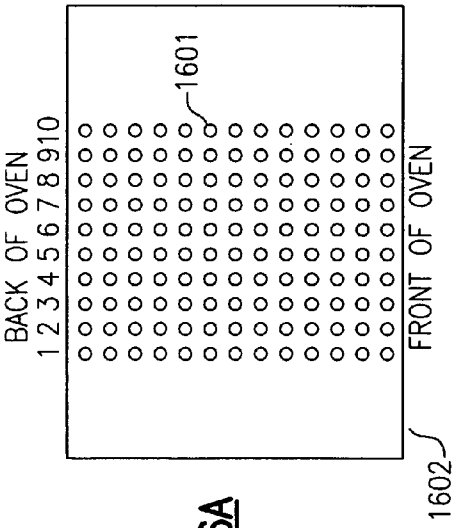


FIG.16A

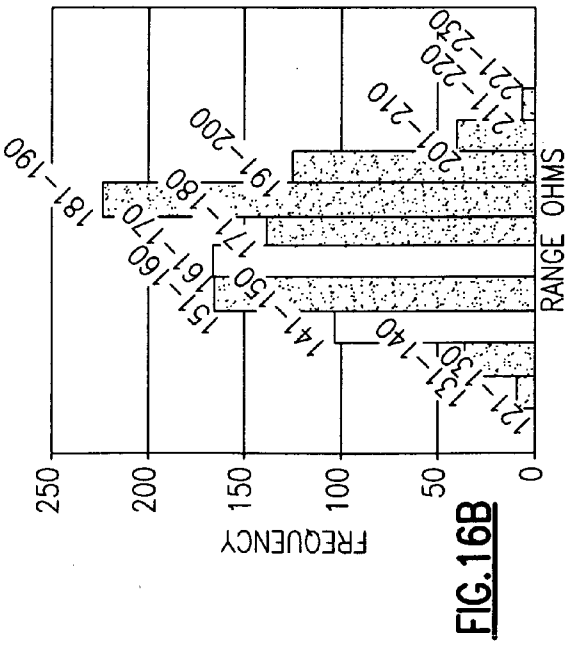


FIG.16B

BODY WORN PHYSIOLOGICAL SENSOR DEVICE HAVING A DISPOSABLE ELECTRODE MODULE

FIELD OF THE INVENTION

[0001] This invention relates generally to a physiological monitor and more particularly to a body worn physiological monitor.

BACKGROUND OF THE INVENTION

[0002] Measurements of various physiological parameters are important to the study of the human condition. Physiological measurements can be particularly important in a health care setting, such as in a hospital. One of the more important physiological measurements performed on a patient is the electrocardiogram (ECG), showing the condition of the human heart.

[0003] Portable patient monitors have evolved that allow patients to enjoy at least some mobility. Typically a battery operated monitor can be hung on a belt, shoulder strap, or carried by a patient using some other similar hanging arrangement. Sensors, such as ECG electrodes, are affixed to the patient's body, such as with tape, and connected to the battery operated monitor by wires. After a fixed interval of time, or at a low battery indication, the batteries can be replaced or recharged. One example of a portable patient monitor is the Micropaq wireless patient monitor, manufactured by Welch Allyn, Inc., that permits multi-parameter monitoring and patient alarm capabilities built in a small, rugged, lightweight, patient-wearable device.

[0004] Another version of a portable physiological monitor is the heart rate monitor typically used by individuals engaged in an athletic activity. The monitor includes a sensor, which generally makes direct or indirect contact with an individual's chest to monitor heart beats and then by wires, or by wireless techniques, the sensor transmits the sensed heart beat to a nearby microcomputer based monitor and display. Such units generally measure only heart beat and are not capable of doing any of the traditional ECG analysis functions.

[0005] A recurrent problem with the portable monitors typically used in healthcare applications is the need for wires from sensors situated on the patient's body to the portable unit. These wires can become tangled and cause discomfort or become unplugged when inadvertently pulled or tugged on. In addition, wire motion can increase ECG noise due to the triboelectric effect. Muscle movement can also increase ECG noise, due to the typical placement of ECG electrodes over major muscles. Moreover, portable monitor battery maintenance (e.g. battery recharging or replacement) can be time consuming and costly.

[0006] Another problem is related to the requirement that a medical grade monitor survive multiple defibrillation cycles of at least 360 joules. Conventionally, this requirement has been met by one or more power resistors situated in series with the wire leads of a fixed or portable physiological monitor. The problem is that the physical volume of conventional power resistors is too large for use in a compact monitor application.

[0007] Another shortcoming of small sensor devices is that these devices lack the intelligence to vary the amount and type of data transmitted, depending on patient condition. Exercise heart monitors do not transmit a full patient waveform for clinical analysis while medical monitors measure and transmit the full patient waveform, even when the patient is healthy. While transmitting the full patient waveform is the preferred solution from a purely clinical standpoint, such transmission requires significant power to transmit large amounts of data and restricts the design from being small and inexpensive.

[0008] Yet another problem is that arrhythmia analysis is a computationally intensive operation not well-suited to existing small portable monitors that presently have no ability to perform arrhythmia analysis.

[0009] Therefore, there is a need for a body worn combined physiological sensor and monitor having a disposable sensor, but used and worn by a patient as a single unit directly and non-permanently affixed to a patient's body. Also, what is needed is a physically compact resistive element for protecting a body worn device from damage caused by multiple defibrillation cycles. Also, what is needed is a medical-grade monitor that can intelligently measure and transmit data only as required to alert clinicians that the patient needs additional attention. What is also needed is a body-worn device capable of running arrhythmia analysis through computationally efficient algorithms.

SUMMARY OF THE INVENTION

[0010] According to one aspect, a body worn patient monitoring device comprises at least one disposable module including a plurality of electrical connections to the body. The electrical connections are coupled to a skin surface of the patient to measure physiological signals of the patient. The at least one disposable module includes a disposable module connector. The body worn patient monitoring device includes at least one internal or external power source to power the body worn patient monitoring device. The body worn patient monitoring device also includes at least one communication-computation module, having a communication-computation module connector to receive physiological signals from the at least one disposable module via said disposable module connector. The communication-computation module also includes at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals and a radio circuit to communicate a raw physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module. The body worn patient monitoring device, including the at least one disposable module and the at least one communication-computation module, is directly non-permanently affixed to the skin surface of the patient.

[0011] According to another aspect, a method of providing high voltage circuit protection for a body worn monitor comprises the steps of: providing a substrate that supports one or more electrical connections to a patient's body; determining a print pattern and thickness of a first material having a first resistivity to be printed on the substrate; determining a print pattern and thickness of a second material having a second resistivity to be printed on the substrate; printing the first

material onto the substrate; and printing the second material onto the substrate wherein at least part of the second material overlays the first material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] For a further understanding of these and objects of the invention, reference will be made to the following Detailed Description which is to be read in connection with the accompanying drawings, in which:

[0013] FIG. **1**A shows an exemplary body worn physiological monitor having a disposable electrode module;

[0014] FIG. **1**B shows a partially unassembled side view of the body worn physiological monitor of FIG. **1**A;

[0015] FIG. **1**C shows an assembled side view of the body worn physiological monitor of FIG. **1**A;

[0016] FIG. **1**D shows a bottom view of the body worn physiological monitor of FIG. **1**A;

[0017] FIG. **2** shows an exploded perspective view of an exemplary body worn physiological monitor;

[0018] FIG. **3** shows an exploded perspective view of an exemplary computation and communication module;

[0019] FIG. **4**A shows an exemplary disposable unit flexible circuit board;

[0020] FIG. **4**B shows a partial enlarged view of a portion of the flexible circuit board of FIG. **4**A, further showing an exemplary resistive trace having a fillet;

[0021] FIG. **4**C shows a partial side elevated view of a portion of the flexible circuit board of FIG. **4**A, further showing an exemplary conductive surface overlaying a resistive material;

[0022] FIG. **4**D shows a partial side elevational view of the circuit board of FIG. **4**A, further showing an exemplary conductive surface having a snap receptacle;

[0023] FIG. **5** shows a block diagram of one embodiment of a body worn physiological monitor having a power source in a disposable unit;

[0024] FIG. **6** shows a block diagram of one embodiment of a body worn physiological monitor having a power source in or connected to the computation and communication module;

[0025] FIG. **7**A shows a schematic diagram of a direct connected reference electrode used in conjunction with a body worn physiological monitor;

[0026] FIG. **7**B shows a schematic diagram of a virtual reference electrode as used in conjunction with a body worn physiological monitor;

[0027] FIG. **8** shows a schematic diagram depicting one embodiment of an analog switching arrangement provided on a body worn physiological monitor to select a reference electrode configuration;

[0028] FIG. **8**A shows an exemplary driven lead circuit topology for use with electrodes of a body worn physiological monitor;

[0029] FIG. **9** shows an exemplary ESIS filter circuit topology with circuit protection;

[0030] FIG. **10** shows an alternative circuit protection to that depicted in FIG. **9**;

[0031] FIG. **11** shows a flow chart for an algorithm utilized by a body worn physiological monitor to detect whether a patient has a pace maker;

[0032] FIG. **12** shows a circuit topology of a high pass filter useful for baseline restoration;

[0033] FIG. **13** shows seven graphs of amplitudes plotted versus frequency to illustrate exemplary operation of the circuit of FIG. **12**;

[0034] FIG. **14** shows two exemplary positions for a body worn ECG monitor to be non-permanently affixed directly to a patient's body;

[0035] FIG. **15** shows a block diagram of a setup for simulating the effect of patient defibrillation on resistive traces;

[0036] FIG. **16**A symbolically shows resistive dots silk screened on a tray;

[0037] FIG. **16**B shows a histogram of an exemplary resistive distribution of baked resistive dots; and

[0038] FIG. **17** shows an exemplary ECG waveform.

[0039] Package styling varies slightly between the drawings. Such minor differences, e.g. the case styling of computation and communication module **102**, illustrate minor variations in mechanical packaging suitable for use as body worn monitors. Drawings are not necessarily shown to scale.

DETAILED DESCRIPTION

[0040] A "body worn" device is described herein with regard to certain exemplary embodiments. A "body worn" device is defined herein as a device that is directly, but non-permanently, affixed to a patient's body. A "body worn monitor" is a device that can be directly "worn" on the patient's body as a single unit, including one or more physiological sensors and a communications and computation module to perform at least initial processing of one or more physiological measurements made using one or more physiological sensors. Unlike prior art patient-wearable devices, at least one sensor can be incorporated into the device that makes a direct or indirect (such as by capacitive coupling) electrical connection with the patient's body without the use of external wires from sensors to the device. In addition and unlike athletic heart monitors, a "body worn" monitor can be a full functioning medical grade monitor, e.g. meeting the requirements of European Unions' Medical Device Directive and other applicable industry standards, such as EC-13 for an electrocardiograph. The body worn medical-grade monitor can include a device, for example, such as a pulse oximeter, CO_2 monitor, respiration monitor, or can function as an ECG monitor, incorporating physiological sensors, front end analog electronic signal conditioning circuits, and a microcomputer based computation unit with wireless reporting of measured physiological data, all contained within in a "body worn" package that can be non-permanently affixed directly to a patient's body. A body-worn medical-grade monitor can also include additional measurement capabilities beyond those mentioned here.

[0041] FIGS. **1**A-**1**D depict various views of an exemplary body worn physiological monitor **100** having a communication and computation module **102** and a disposable electrode module **110**. In this exemplary embodiment, physiological monitor **100** is designed for use as an electrocardiogram (ECG) monitor for obtaining and recording and/or transmitting ECG information, including ECG waveforms and alarms for a person, such as a patient, wearing body worn physiological monitor **100**.

[0042] FIG. **1**A shows an exemplary top view of body worn physiological monitor **100**. A crescent shape allows the body worn physiological monitor **100** to be placed on the chest of a patient, and more specifically around the pectoralis major, to allow measurement of lead configuration I, II, or III, or to be placed on the patient's side allowing measurement using a V-lead configuration. Though not shown, multiple body worn physiological monitor **100** units can be used to effectively provide multiple leads. By placing electrodes around the

body so that they are not situated directly atop major muscles, both motion noise artifacts and muscle noise artifacts can be prevented. Moreover, by eliminating cables, noise due to cable motion or compression (i.e. triboelectric effect) can be eliminated.

[0043] FIG. **1**B shows a side elevated view of physiological monitor **100** having an exemplary attachment mechanism, such as a retention clip **104**, to mechanically attach communications and computation module **102** to the top surface of the disposable electrode module **110**. Flexible printed circuit layer **101** can be made from a thin insulating material, such as according to this embodiment, a 75 micron thick layer of Mylar®. Typically electrical traces (not shown in FIGS. **1**A-**1**D) on flexible printed circuit layer **101** can be further protected by an insulating covering, analogous to a conformal coating. A formed plastic layer or a cloth with adhesive on one side thereof can be used to cover and protect flexible printed circuit layer **101**, as well as to provide an aesthetic outer layer to make the body worn monitor **100** visually appealing.

[0044] FIG. **1**C shows a side view of physiological monitor **100** in which the communications and computation module **102** has been affixed to disposable electrode module **110**. FIG. **1**D depicts a view of the underside of exemplary physiological monitor **100** showing one embodiment of disposable electrode module **110** having electrodes **109**. In this embodiment, each electrode **109** comprises electrode gel **103** and conductive surface **404** (FIG. **4**). Together, electrode gel **103** and conductive surface **404** create a half-cell, such as, for example, a Silver/Silver Chloride half cell. Also and according to this embodiment, conductive surface **404** can directly accept the electrode gel **103**.

[0045] FIG. **2** shows an exploded assembly view of the exemplary body worn physiological monitor **100**. As noted with regard to FIGS. **1**A-**1**D, the body worn physiological monitor **100** includes a removable and reusable communications and computation module **102** and a disposable electrode module **110**, the later including electrode gels **103** for ECG monitoring and batteries **204** to power communications and computation module **102**. A flat planar insulating/adhesive member **105** includes a plurality of openings that are each sized to receive electrode gels **103**. The insulating member **105** provides a bottom side cover for the flexible printed circuit layer **101** and augments adhesion to the human body. Electrode gel **103**, when attached to an appropriate substrate such as silver-silver-chloride or other substrate, can be used to establish a relatively low impedance electrical connection between conductive surface **404** (FIG. **4**) and the patient's skin.

[0046] Electrode gels **103** can adhere to a patient's skin. While electrode gel **103** is typically an adhesive electrode gel, the adhesion offered by electrode gels **103** alone might not give a sufficient holding force for non-permanently affixing body worn physiological monitor **100** to a patient. To achieve a better adhesion of body worn monitor **100** to a patient's skin, insulating/adhesive member **105** can be used to non-permanently affix body worn physiological monitor **100** to a patient. Thus, body worn monitor **100** can be applied to a patient in the same way an adhesive strip is applied, such as for example, those adhesive strips sold under the brand name "BAND-AID®". One exemplary type of foam adhesive suitable for affixing a flexible circuit board to a patient is 1.6 mm adhesive foam from Scapa Medical of Bedfordshire, UK. As shown in FIGS. **1**B and **1**C (although not to scale), each of the electrode gels **103** extend sufficiently below adhesive layer **105** in order to ensure good electrical connection with a patient's skin surface (not shown). Tab **106**, FIG. **1**A, allows for easy removal of a protective backing **111** from adhesive layer **105**.

[0047] Flexible printed circuit layer **101** can include contacts, such as battery clips (not shown), to receive and connect to batteries **204**. (It is contemplated that in some future embodiments, a single battery can provide sufficient electrical power.) In the exemplary embodiment, as shown in FIG. **2**, batteries **204** can be mounted under respective battery flaps **205** arranged on opposite sides of the flexible printed circuit layer **101**. Alternatively, battery clips (not shown) or battery holders (not shown) can be used to provide both mechanical support and electrical connections for each of the batteries **204**. One type of battery holder suitable for such use, for example, is the model 2990 battery holder, manufactured by the Keystone Electronics Corp. of Astoria, N.Y. Battery cover **107** provides protection for batteries **204** as well as a surface to press upon when applying electrodes **103** to conductive surface **404**. Retention clips **104** can comprise, for example, a plurality of spring fingers with latching clips. Retention clip **104**, affixed to disposable electrode module **110**, can be used to secure reusable communications and computation module **102** to disposable package **110**. Reusable communications and computation module **102** is herein illustrated in a simplified representation, including cover **201**, communications and computation printed circuit board assembly **202**, and base **203**.

[0048] FIG. **3** shows a mechanical view of an exemplary reusable communications and computation module **102**, as well as a preferred method for making an electrical connection between flexible printed circuit layer **101** in disposable electrical module **110** and communications and computation printed circuit board assembly **202** situated in reusable communications and computation module **102**. In this exemplary embodiment, communications and computation printed circuit board assembly **202** can include a plurality of press fit and/or soldered conductive sockets **301** for receiving electrical plug **302**, the plug having a corresponding plurality of conductive pins. Each conductive pin shown in plug **302** can correspond to an electrical connection pad on flexible printed circuit layer **101**. A row of mechanical sockets **303** can receive the multi-pin row of plug **302**. Thus, an electrical connection can be made between each pad of flexible printed circuit layer **101** having a conductive post on plug **302** and each corresponding conductive socket **301** on communications and computation printed circuit board assembly **202**. Posts **304** can align and secure each of the cover **201**, communications and computation printed circuit board assembly **202**, and base **203**. Note that in FIG. **3**, a simplified drawing of cover **201** omits slots to receive retention clip **104** to affix communications and computation module **102** to disposable package **110**. A body worn monitor **100** would typically also include retention clip **104** FIG. **2**, or other suitable type of mechanical clip(s), in order to provide a secure mechanical connection between communications and computation module **102** and disposable electrode module **110**.

[0049] FIG. **4**A shows one embodiment of flexible circuit board **101** in an expanded (e.g. unassembled) view. Flexible circuit board **101** is formed on a substrate **406**. Substrate **406** can be cut, for example, from a Mylar sheet of suitable thickness. In this embodiment, one battery **204** can be mounted adjacent to an conductive surface **404**. Conductive gel **103**

(not shown in FIG. **4**) can be mounted on the exposed conductive side of a conductive surface **404**.

[0050] Conductive surface **404** can also be viewed as the electrode portion of a half cell and electrode gel **103** can be considered to be the electrolyte portion of a half cell. In conventional terms of art, the combination of electrode and electrolyte and ECG electrode is typically referred to as a half cell. For example, the combination of a conductive surface **404** and an electrolyte layer (e.g., electrode gel **103**) forms a half cell. For convenient quick reference to a half cell structure, the term "electrode" (assigned reference designator "109") is used interchangeably with "half cell" herein. It is understood that in typical embodiments, electrode **109** comprises conductive surface **404** and electrode gel **103**.

[0051] Typically, electrodes make use of a circular or square conductive surface. Increasing the ratio of the perimeter of the surface to the area of the surface affects current density distribution and defibrillation recovery.

[0052] For convenience, we define the term "annulus" herein and throughout as the region between two simple curves. A simple curve is a closed curve that does not cross itself. Under this definition, an annulus can include substantially square shapes, substantially rectangular shapes, substantially circular shapes, substantially oval shapes, as well as substantially rectangular shapes with rounded corners. Further we include in the definition of annulus, the case of a substantially "U" shaped surface as described by a single closed curve.

[0053] One exemplary electrode gel **103** suitable for such use on a body worn monitor is type LT00063 hydrogel supplied by Tyco Healthcare of Prague, Czech Republic. Typically, a conductive surface **404** creates the electrode portion of the half-cell. By increasing the ratio of perimeter to area of the circular electrode portion of the half cell, the signal to noise ratio of the input ECG signal can be increased.

[0054] As depicted herein on the exemplary circuit layout, two batteries **304** can be connected in series, with one polarity being made available at connection pad **407** from battery connection **402**, battery connection **401** creating the series connection between the two batteries, and connection pad **410** providing the second polarity of the series connected batteries. Note that in some embodiments, a single battery alternatively may be used in lieu of the exemplary arrangement or two batteries can be also wired in parallel, depending on the voltage requirements of a particular communications and computation module **102**.

[0055] Connection pads **408** and **409** electrically couple the signals from electrode gels **103** (not shown in FIGS. **4**A-**4**D) via conductive surface **404** and resistive traces **412** to electrical plug **302** (not shown in FIGS. **4**A-**4**D). Electrode contact pad **405** can be connected via resistive trace **413** to connection pad **411** to provide a direct-connected reference electrode (not shown in FIGS. **4**A-**4**D). Traces **412** extending between conductive surface **404** and connection pads **408** and **409** and trace **413** extending between conductive surface **405** and connection pad **411** can be made from resistive materials including resistive metals, carbon, silver ink, powders, paints, or other material of determinable electrical resistance.

[0056] Resistive traces on flexible circuit board layer **101** replace the bulky power resistors needed by prior art monitors, having electrodes or sensors connected by wires or leads. These resistive traces should survive multiple defibrillation cycles such that body worn monitor **100** remains functional even after one or more attempts to re-start a patient's heart. In order to survive defibrillation, the resistive traces should dissipate that portion of the potentially damaging defibrillation energy that is coupled into the monitor. This fractional portion of the defibrillation energy typically enters body worn monitor **100** from electrodes **109**, FIG. **1**D (electrodes **109** including conductive surface **404** and electrode gel **103**).

[0057] It is desirable that the resistances of the protective resistive traces be in a range between about 1 kilo ohm to about 10 kilo ohms. Below 1 kilo ohm, depending on the resistive material used, it can be more likely that the resistance of the resistive traces **412** and **413** will increase with each successive defibrillation pulse. Above 10 kilo ohms, a high resistance impairs the signal to noise ratio, specifically due to thermal noise, which has a mean square value of 4*k*T*R*BW, where "k" is Boltzmann's constant, "T" is temperature measured in degrees Kelvin, "R" is resistance in ohms, and "BW" is bandwidth, in Hz, which becomes significant relative to the EC-13 requirement that the noise referred to input be less than 30 μV peak-to-valley.

[0058] Power dissipation in the herein described traces can be calculated by E^2/R, in which E refers to the potential across the trace and R is the resistance of the trace. R can be calculated by ρ*L/A, where ρ is the resistivity of the material used to form the trace, L is the length of the trace, and A is the cross-sectional area of the trace.

[0059] In developing resistive traces for use on a flexible printed circuit layer **101**, typically formed on a Mylar substrate **406**, such as shown in FIG. **4**A, various materials were tested. Silver, including silver inks, while useable, was found to be less desirable, because it was difficult to achieve sufficiently thin silver traces on Mylar to achieve high enough resistances. Carbon, including carbon pastes and carbon inks, was also tried and found to be suitable. In order to use carbon however, several additional problems had to be solved. At 1 kilo ohm, the power dissipated by the resistors caused them to degrade across multiple defibrillation cycles. The solution was to make carbon traces in the range of about 8 to 10 kilo ohms. 10 kilo ohm resistances proved to be a good compromise between noise levels, power dissipation by the resistors, and manufacturing tolerances for depositing carbon ink on a Mylar substrate to dissipate the power from multiple defibrillation cycles. To achieve the desired resistance of about 10 kilo ohms (interchangeably represented herein as "10 k" or "10 kΩ"), for a given resistivity of the carbon paste, and given trace width and thickness (height), the length of the trace is then defined. In some cases, such as for traces **412**, the length needed for a trace run, as between conductive surface **404** and connection point **409**, might be longer than the length defined for a particular trace resistance (typically 10 k). In this case, traces can be extended by lengths of silver conductive traces. There can be a short overlay distance, on the order of 5 to 10 mm, in which a silver trace overlaps the carbon trace to provide a more robust connection between the resistive and conductive portions of the traces. Where overlap is used, the overall length of the resistive portion can be adjusted slightly to maintain the desired overall resistance.

[0060] Another problem associated with carbon traces was arcing at the interface between the carbon and conductive traces. Arcing was particularly problematic at the abrupt connection between the carbon trace and conductive surface **404**. Arcing was also observed to occur between the end section of the carbon trace and conductive surface **404**. (Electrode gels **103** create the conductive path to the patient through conductive surface **404** and a layer of conductive gel.)

[0061] According to one solution to the above noted arcing problem, as shown in FIG. **4**B, a rounded (fillet) section **430** of carbon trace can be added at the interface to conductive surface **404**. A fillet or "tear drop" shape causes the carbon trace to become gradually wider as it connects to conductive surface **404** and relieves the electrical potential stress at the interface.

[0062] An alternative solution to the arcing problem is shown in FIG. **4**C, wherein carbon can be laid down beyond the trace (**412**) to include a pattern of conductive surface **404** formed from carbon. A carbon annulus pattern can be deposited before the conductive surface **404** is deposited. Conductive surface **404** can then be deposited as an overlay over the earlier formed carbon annulus shape. Finally, conductive gel **103** can be attached to the conductive surface layer (the carbon layer residing between conductive surface **404** and the Mylar substrate used as flexible circuit board **101**). Both of the aforementioned arcing solutions can be used together. It should also be noted that conductive surface **404** can be formed from suitable materials other than silver, including, for example, materials such as silver chloride.

[0063] Arcing can also occur between the resistive traces and other (typically silver) conductive traces on the flexible circuit board **101**. Trace to trace arcing can be suppressed by allowing sufficient spacing between the traces. Generally a minimum spacing of about 3 mm/kV, as required by ASNI/AAMI DF80:2003 57.10 BB, has been found to be sufficient to prevent trace to trace arcing from a defibrillation event. Closer trace spacing, as close as 0.01 mm/kV, can be employed successfully by first applying an insulating dielectric layer, similar to a conformal coating, over the surface of flexible circuit board **101** that covers most of the substrate and traces. The insulating dielectric layer can be prevented from forming or adhering to conductive surface **404**, such as by use of a mask during application of the insulating layer.

[0064] In an alternate embodiment, as depicted in FIG. **4**D, a snap device can be added to conductive surface **404** to accept a manufacture snap-on electrode (not shown), such as, for example, the ConMed Cleartrace line of ECG electrodes including the model 1700 Cleartrace electrode manufactured by the ConMed Corp. of Utica, N.Y. or similar type electrodes made by the 3M Corp. of St. Paul, Minn. When designed to accept a snap-on electrode, the conductive surface **404** is typically smaller than in the previous embodiment. A receptacle snap **432** for receiving the commercial snap-on electrode can be inserted by any suitable method, such as by press fitting or other fastening method, into conductive surface **404**, typically also penetrating through substrate **406**. In this embodiment, arcing can be similarly suppressed in this embodiment by adding a fillet to the carbon-conductive surface interface and/or deposing a conductive surface **404** over a carbon layer as previously described.

[0065] Example: Resistive traces and an annulus were tested on a substrate formed from CT3 heat stabilized treated polyester (75 microns thick), such as manufactured by the MacDermid Autotype Corp. of Schaumburg, Ill. Resistive traces were silk screened onto the substrate using 7102 carbon paste conductor from the DuPont Corporation of Wilmington, Del. The carbon paste conductor was deposited through a 43T silk screen mesh. The substrate containing the paste deposit was then cured inside a fan assisted air circulated oven at 120° C. for a period of 5 minutes. The traces formed were about 55 mm long and 2 mm wide, having an overall thickness of about 7.5 microns. The initial measured resistance of each trace was about 14 kilo ohms. After each trace was subjected to 3 defibrillation cycles, the measured resistance increased to about 15 kilo ohms. Over a 3 mm length, the trace widens to about 5 mm, terminating into a carbon annulus with an outer diameter of about 20 mm and an inner diameter of about 10 mm. A silver layer of PF-410 silver ink from the Norcote Corp. of Eastleigh Hampshire, UK was then deposited over the carbon annulus, also to an overall thickness of about 7.5 microns. The deposition of the silver layer was via the silk screen printing method, in which a 90T silk screen mesh was used. The substrate containing the deposited silver ink was then cured inside a fan assisted air circulated oven at 120° C. for a period of 15 minutes. A third dielectric insulating layer comprising SD2460, components A & B (dielectric and hardener), manufactured by Lackwerke Peters GmbH+Co KG of Kempen, Germany, and having a thickness of approximately 13 microns was then deposited over the traces and substrate, but not over the annulus. (The electrodes were formed by attaching a conductive gel to the annulus. The conductive gel used was LT00063 hydrogel from Tyco Healthcare of Prague, Czech Republic.) Again, the silk screen printing process was used to deposit the dielectric layer through a 90T screen mesh. The substrate was placed again into a fan assisted air circulated oven at 120° C. for a period of 30 minutes.

[0066] Example: Silver traces for use as conductive (not resistive) traces on a body worn monitor circuit substrate were formed from a silver paste that was silk screened onto a Mylar substrate. 45 mm long traces had a measured resistance in a range of 3.5 to 6 ohms, 75 mm traces had a measured resistance in a range of 6.5 to 13 ohms, and 105 mm traces had a measured resistance in a range of 10 to 16 ohms. The deposition of the silver layer was performed via the silk screen printing method in which a 90T silk screen mesh was used. The substrate containing the deposited silver ink was then cured inside a fan assisted air circulated oven at 120° C. for a period of 15 minutes.

[0067] FIG. **15** diagrammatically depicts an exemplary test setup used to simulate the effect of a patient defibrillation on resistive traces. Defibrillator **1501** was used to apply multiple defibrillation shocks of 360 Joules each to the 100 ohm resistor **1502**. The 100 ohm resistor according to this setup simulated a patient's body. Note that most of the defibrillation energy goes into the patient's body by design, to restart the patient's heart. Resistive traces **1503** and **1504** were wired across resistor **1502**, also as shown in FIG. **15**, in order to simulate the electrical circuit that would be formed between the resistive traces in a body worn monitor situated on a patient undergoing defibrillation. Neon bulbs **1506** were used as part of the protection circuitry that can be used with resistive traces in a body worn monitor. 400 ohm safety resistor **1505** was present as a precaution to limit short circuit current in the event of a test setup failure. Both the 100 ohm resistor (simulating human skin resistance) and the 400 ohm safety resistor were used in accordance with medical specification AAMI EC-13. Following 3 defibrillation shocks of 360 Joules each, the measured resistance of the 10 k carbon track changed from 10 k to 11 k following the first shock, to 13.1 k following the second shock, and to 13.2 k following the third shock. The measured resistance of the 9.7 k trace changed from 9.7 k to 11.6 k following the first shock, to 13.0 k following the second shock, and finally to 13.2 k, following the third shock. In a subsequent related test, the 100 ohm resistor was replaced by a closer simulation in the form of a

fresh (dead) chicken. The setup otherwise remained the same as shown in FIG. **15**. In this case, the resistance as measured on each of the test resistive traces changed from 10.7 k to 10.25 k, and from 8.5 k to 9.4 k, following multiple defibrillations. During testing, it was also noted that the change in measured resistance of the resistive traces was generally consistent. It was also noted that as a given resistive trace was increased, the (delta R {caused by defibrillation}/R {net trace resistance}) can be minimized.

[0068] The screen printing technique for laying down resistive traces was further investigated by printing a plurality of small carbon resistive dots **1601** of about 20 mm in diameter using a 7102 carbon ink applied by a screen printer (not shown). The carbon dots **1601** were laid out on a tray **1602** as shown in FIG. **16**A, for baking in an oven. A manually operated squeegee (not shown) was used to apply the resistive dots **1601** to the tray **1602** through a mask (not shown). It was determined that control of thickness during application was one important factor for controlling the distribution of resistance. It was noted that during manual application, the variation of resistance depended upon the distance between the plurality of dots **1601** and the person applying the resistive paste, and that the pressure applied using the squeegee could also affect the final resistance by a factor of two. It was further noted that "even" heating across the tray **1602** was advantageous during oven drying, although this factor was found to have less effect on the final dot resistance distribution. A resistance distribution of the baked and measured dots **1601** is shown in the histogram of FIG. **16**B. This testing indicated that production traces laid down on a substrate, such as Mylar, for use in a body worn monitor should preferably be printed using a semi-automatic screen print process, such as by a screen printing mechanical roller process. A digital multimeter ("DMM") with probes placed at each edge of a dot **1601** was used to measure the resistance from one edge of the dot to the other. It was found that uniform application of ink was important to keeping a tight distribution of resistance, with even heating having a smaller influence on the distribution of the resistance of the test dots. Since a trace with too low a resistance has a greater $\Delta R/R$, and higher probability of failing and very high resistance traces result in worse S/N ratio, it is important to have a reasonably tight tolerance on the trace resistance.

[0069] FIG. **5** shows a block diagram representative of one embodiment of the body worn physiological monitor **100**. Physiological sensors **501** (such as electrodes **109** in FIG. **1**D) can be electrically coupled to electromechanical connector **502** (as by the resistive traces **412** shown in FIG. **4**). Connector **502** serves to electrically couple communications and computation module **102** to a disposable electrode module **110** (FIG. **2**). Secondary connector **503** can also electrically couple one or more additional sensors, which can be situated both on and off of disposable electrode module **110**, to electromechanical connector **502** for electrical coupling along with physiological sensor signals **501** to communications and computation module **102** (shown in FIG. **1**) via electromechanical connector **505**. Signals received by the communications and computation module **102** can be electrically coupled into communications and computation module **102** via electronic protection circuits **506** and/or filters, such as ESIS filters **507**.

[0070] Signals can be limited or clipped in amplitude, as needed, by protection circuit **506**, and filtered by filter **507**. One or more analog amplifiers **508** can be used to amplify the amplitude limited and filtered signals. In the exemplary body worn ECG monitor, amplifiers **508** can advantageously be differential amplifiers to amplify the difference signal (e.g. the ECG "vector") between two ECG electrodes. The electrical output of amplifiers **508** can be electrically coupled to both PACER circuits **509** and ECG circuits **510**. PACER circuits **509** are described further below. ECG circuits **510** perform several functions, including "trace restore", low pass filtering (anti-aliasing), high pass filtering, and amplification (gain). Low pass filtering filters signals according to the Nyquist criterion to avoid aliasing later when the signals are digitized by analog to digital converter (ADC) **516**. The high pass filter causes the input to be AC coupled from a roll off frequency of about 0.05 Hz, as specified by industry ECG standards. Gain is required to cause the small pre-amplified potentials from physiological sensors (such as electrodes **109**) to more closely match the available dynamic range of the digitizing ADC **516**. Note that ADC **516** can be a dedicated ADC chip or can be included in a microcomputer integrated circuit, such as a microcomputer serving as microprocessor **512**.

[0071] A microprocessor, such as microprocessor **512**, is defined herein as synonymous and interchangeable with the terms "microcomputer", "microcontroller", and "microprocessor". Such microprocessors are also interchangeably represented herein as "μP" or "μC". Further, any microprocessor disclosed herein can be replaced by any integrated device that can perform the function of a microprocessor, such as, but not limited to, a field programmable gate array ("FPGA") programmed to perform the functions of a microprocessor.

[0072] Typically, one or more differential amplifiers can be dedicated to particular difference voltages associated with physiological sensors **501** or **504**, but it should be noted that one or more amplifiers **508** can also be multiplexed by techniques as known in the art, to serve multiple physiological sensors using a lesser number of amplifiers. Similarly, one or more ADCs **516** can serve two or more signals from physiological sensors **501** or **504** using techniques such as multiplexing in time that is digitizing one physiological sensor difference signal at a time sending a digital result to a next stage one after the other. ECG circuits **510** and PACER circuits **509** are referred to in the plural, since there can be individual circuits for each measured physiological signal, such as for each measured ECG vector.

[0073] Electrical power from power source **515** can be regulated by regulator **514** and distributed as regulated voltage **517** to most function blocks (as represented herein by the label "POWER"). Each of these function blocks also has a control ("CTRL") input **511** from microprocessor **512**, allowing these circuits to be disabled, when not needed, in order to save battery power. When viewed over time, most of the ECG waveform does not contain useful information since there is significant "dead time" between heart beats. Therefore, for example, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, circuits can be powered down (in a device "sleep mode") to save on the order of 60% of the energy stored in the power source that would have otherwise been used during this dead time.

[0074] FIG. **17** shows an exemplary ECG waveform. In brief, the P wave can be related to the electrical current causing atrial contraction. The QRS complex can be related to ventricular contraction of the left and right ventricles. The Q wave can be related to electrical current traveling through the

intraventricular septum, while the R and S waves can be related to the ventricles contracting. The T-wave is due to the re-polarization of the ventricles. Usually, atrial re-polarization occurs atop the QRS complex, and being much smaller than the QRS complex, is not seen. The ST segment connects the QRS complex to the T-wave. Irregular or missing waves may be indicators of cardiac issues including: ischemic tissue, e.g. due to myocardial infarction, bundle branch block, atrial problems (specifically P-wave abnormalities), pericarditis, and electrolyte disturbance.

[0075] Generally, power source **515** can include one or more "button" cells typically disposed on disposable electrode module **110**; however, the block diagram of FIG. **6** shows an embodiment of a body worn physiological monitor **100** where power is supplied by a power source located on, or connected to communications and computation module **102** instead of residing within disposable electrode module **110**.

[0076] Beyond power saving considerations, it can also be desirable in some embodiments of body worn physiological monitor **100** to put the microcontroller and/or other circuits, including particularly digital circuits, into a sleep mode during an ADC conversion cycle to minimize pickup of self generated electrical noise and to minimize power use. Preferably, the A/D circuit can acquire multiple samples and buffer the samples, before awakening the microprocessor, which then can batch-process the data. Buffering can be set to match the patient's heart rate, as there is no significant clinical benefit to analyzing every sample as it is taken.

[0077] Turning back to the input circuits, typically amplifiers **508** are differential or instrumentation amplifiers useful to selectively amplify desired difference signals between connector terminals (such as an ECG vector), while rejecting common mode signals (such as interfering signals that appear simultaneously on both connector terminals). Beyond using a differential amplifier, other techniques can be advantageously used to further reduce common mode pickup (CMR) and thus to improve the common mode rejection ratio (CMRR) of the input amplifier stages of body worn physiological monitor **100**. CMR is of particular concern with regard to body worn physiological monitor **100** because of the proliferation of potentially interfering electromagnetic fields, such as from 50 Hz or 60 Hz AC power line distribution throughout a hospital. For example, many fluorescent ceiling lamp fixtures generate strong 60 Hz alternating current (AC) electromagnetic fields that can appear as common mode signals on physiological sensors **501**, such as ECG electrodes **109**.

[0078] FIG. **7**A shows one embodiment in which body worn physiological sensor **501** comprises a plurality of ECG electrodes **109** and **701**. Two electrodes **109** generate an ECG difference potential for patient **703**. A third electrode, reference electrode **701** can be electrically coupled to electronics common **704** (or other potential level) and can be used to improve CMR. In this embodiment, the electronics common **704** (shown as the negative terminal of the battery in FIG. **7**A) can be directly tied to the patient in the vicinity of electrodes **109**. Thus, the electronics common of the electronic circuits in communications and computation module **102** can be made to more closely follow any change in potential in the vicinity of electrodes **109**. Reference electrode **701** can be particularly helpful to ensure that inputs **109** remain within a reasonably narrow common mode range, such as by reducing a 60 Hz potential that would otherwise appear to move the electronics common **704** at 60 Hz with respect to electrodes **109**.

[0079] In another embodiment as shown in FIG. **7**B, virtual electrode **702** performs a similar function as previously described with regard to reference electrode **701**. In this embodiment, instead of creating a DC-coupled reference electrode, electrode **701** is replaced by the capacitive coupling between flexible printed circuit layer **101** and the patient **703**, resulting in a virtual electrode **702** with an AC coupled common. Such AC coupling increases with decreased distance between flexible printed circuit layer **101** and the patient and can advantageously reduce 60 Hz common mode signals (AC signals).

[0080] In yet another version of a directly connected electrode **701**, as shown in FIG. **8**A, electrode **701** can be actively driven by an electrical output from communications and computation module **102**. Typically, an operational amplifier (OpAmp) or other type of amplifier can be used to create a "driven lead". Driven lead circuits can be used to further improve CMR over passive electrodes **701** as shown in FIG. **7**A. An exemplary circuit suitable for use to drive an electrode **701** is shown in FIG. **8**A. Amplifiers (OpAmps) **810** and **811** buffer the high impedance signals from electrode **1** and **2** (exemplary electrodes **109**). Difference amplifier **508** conveys the difference signal (such as an ECG vector) as previously described. The two 10 kilo ohm resistors provide an average of the common mode signals appearing simultaneously at the inputs of buffer amplifiers **810** and **811**. The inverting low pass filter built around OpAmp **812** inverts the averaged common mode pickup signal (at electrodes **1** and **2**) and applies that signal out of phase (180 degree phase shifted) to a directly connected driven electrode (such as electrode **701**). By applying the average common mode signal to the driven electrode, amplifier **812** effectively suppresses common mode signals at electrodes **1** and **2** within the effective bandwidth of the negative feedback loop by active noise cancellation. In theory, a virtual electrode **702** could be similarly driven, but the voltage requirements to drive a capacitively coupled common electrode are high enough to make a "driven virtual electrode" a less practical option. Thus, it can be seen that a reference electrode can be a passive connection or an actively driven connection.

[0081] It can also be desirable to have more than one CMR technique available. For example, in a low noise environment, a lower power reference electrode might be used for CMR. Then if the noise increases to a level where the reference electrode provides insufficient CMR, the body worn monitor can switch to a driven lead more suitable for CMR in a high noise environment. In this embodiment, a particular CMR configuration can be selected by electronic switching. FIG. **8** shows one such exemplary switching block represented as reference electrode switch **801**. Microprocessor (μP) **512** can control reference electrode switch **801** to select direct connected electrode **701**, virtual electrode **702**, or directly connected electrode **701** additionally driven by a driven lead circuit **802**. It should also be noted that in the embodiment of FIG. **8**, when virtual electrode **702** provides sufficient CMR, electrode **701** can be used as a third electrode, thus allowing body worn monitor **100** to simultaneously measure two different heart vectors.

[0082] FIG. **9** shows one embodiment of an exemplary defibrillation protection circuit (**506**) and ESIS filter **507**. As shown in FIG. **9**, electrodes **109** can be connected via input resistors R**91** and R**92**. Gas discharge tubes, such as neon bulbs L**1** and L**2**, can be used for over voltage protection by firing at a designed voltage to prevent large potentials from

appearing at the input leads to amplifier **508**. The gas discharge tubes can be disposed on either disposable electrode module **110** or on the communication and computation module **102**. Defibrillation protection resistors R**91** and R**92** can further reside in disposable electrode module **110**, such as in the form of the resistance of traces **412**.

[0083] ESIS filters **507** can be used to satisfy AAMI standard EC13 on Electrosurgical Interference Suppression (ESIS). Standard EC13 addresses the ability of an ECG monitor to display and process ECG signals in a satisfactory manner while connected to a patient on whom an electrosurgical device is being used. Without such suppression, the high RF output of an electrosurgical device can render ECG monitoring impossible and or render the monitor unusable. Resistors R**93** to R**98** and capacitors C**91** to C**96** form cascaded low pass filter sections (e.g. R**93**-C**1**). Three cascaded single pole filters are shown on each input leg of amplifier **508** as an example; more or less stages can also be used. It is also not necessary for each section of the cascaded filter to have identical values or roll off points in the frequency domain to create a specific response, e.g., Bessel, Chebychev, or other filter response known to those skilled in the art. Also, ESIS filters are not limited to cascaded single pole filters and can take other forms as known in the art.

[0084] Test circuit **906** can provide a relatively sharp transient signal for testing the PACER circuit described below as part of a body worn monitor **100** "power on self test". Resistors R**99** and R**100** can pull the output of the differential amplifier **508** allowing the microcontroller (**512**) to detect which electrode, if any, has detached, much as a "lead failed" detection is accomplished by ECG monitors having leads. Body worn monitor **100** does not use leads, but it is still possible for one or both of the physiological sensors to move free of a patient's body. Such disconnects can occur in situations in which body worn monitor **100** partially moves away from the body to which it is non-permanently affixed. The input impedance at one or both of the electrodes **109** changes in a sensor off (sensor disconnect) event. When a patient is attached, amplifier **508** typically has an output voltage of near zero volts. However, if one of the electrodes **109** comes off, resistors R**99** or R**100** cause the output of amplifier **508** to move to a most positive output ("positive rail") or to a most negative output ("negative rail"). Note that the negative rail can be a small voltage near zero, in the case of single supply circuit operation, and that both inputs could be pulled to the same rail. Lead-fail detection can also be analyzed to determine when the device is attached to the patient and then to automatically enter full operational mode. Such analysis can be done at a low frequency.

[0085] The ESIS filter **507** also can cause a stretching in the time domain of a pacer pulse so that the event is recorded by at least one sample, even though the pacer pulse itself is of small duration compared to the ADC sample rate and the pacer pulse is likely to occur between samples.

[0086] FIG. **10** shows an alternative circuit to accomplish over voltage protection, such as is required during defibrillation. In FIG. **10**, diodes **1001** prevent the electrode potentials from going much more than one diode voltage drop above Vcc or below ground and resistors R**91** and R**92** limit current. Using circuit protection, such as gas discharge tubes L**1** and L**2** (FIG. **9**) and/or diodes **1001** (FIG. **10**) combined with resistances R**91** and R**92**, typically in the form of resistive traces **412**, a body worn device can survive multiple defibrillation cycles of at least 360 joules.

[0087] PACER circuit **509** detects pacemaker pulses. One reason to detect a pacemaker is to prevent the ECG circuitry from inadvertently registering the regular pulses from a pacemaker as an actual heart rhythm. Separation of a pacemaker signal from signals generated by the heart is important both to generate accurate ECG analysis results as well as to correctly detect the absence of an actual heart rhythm. For example, a pacemaker continues to function even where a human heart has completely failed.

[0088] A pacer event (pacemaker signal) is typically a narrow pulse typically less than 100 microseconds wide. Because of the capacitance between the pacer in a patient and an ECG circuit, an otherwise relatively square pacer pulse as administered at the patient's heart by a pacemaker, can appear to an ECG monitor as a pulse with a negative undershoot and an exponential return to zero that could inadvertently mimic a QRS signal. A pacer signal, however, can be recognized by an analog differentiator and alert microprocessor **512** to the presence of a pacer and to disregard the refractory period of the corresponding R-C recovery due to the pacer signal. The pacer detection circuit or PACER circuit can generate a microprocessor interrupt to inform the microprocessor that a pacer event occurred and to mark a corresponding physiological signal in time as related to a pacer event. PACER circuit **509** can also cause one or more pacer related circuits to automatically power down for power saving, where it is determined that a patient is not using a pacemaker.

[0089] FIG. **11** shows an algorithm useful to determine if the pacer circuit should be enabled. A typical PACER detection circuit uses a significant percentage of the energy available from a power source such as batteries **204**. If a PACER signal is not detected, such as at power up of body worn monitor **100**, the pacer circuit can be automatically disabled allowing for a longer battery life. Since typical PACER circuits can use several amplifiers (OpAmps), they can consume up to one third of the analog power, therefore securing the PACER circuits when they are not needed (i.e. the patient does not have a pace maker) can cause a significant improvement in battery life. The algorithm also can also provide checks to determine if a demand type pace maker begins operation (which might be inactive at power up of body worn monitor **100**) by analyzing beat variability. While it can be advantageous to have the body worn device automatically sense the presence of a pacemaker and to enable the PACER detection circuit, the choice as to whether to enable or disable the PACER circuit can also be done by externally configuring the body worn device. Such external configuration can be done through a hardwired communication connection cable or via communications and computation module **102**, in which communications and computation module **102** is a two-way radio transceiver communication device capable of receiving a configuration command sent for a remote radio transceiver. The radio could be 802.11 compliant, but generally would use a lighter-weight (simpler) protocol that can be more energy efficient. A suitable lighter weight protocol could be proprietary, or standards-based, such as ZigBee or Bluetooth. A body worn physiological monitor **100** is particularly well suited for use in hospital environment as part of an integrated wireless monitoring network. The details of such monitoring networks are disclosed in U.S. patent application Ser. No. 11/031,736 entitled, "Personal Status Physiological Monitor System and Architecture and Related Monitoring Methods", which is incorporated by reference herein in its entirety.

[0090] FIG. **12** shows a high pass filter (HPF) suitable for use in ECG circuits block **510**. An advantage of a 0.5 Hz HPF is faster recovery from DC offsets due to patient movement, defibrillation, electrocuatery, etc. However ST segment analysis is negatively impacted if HPF cutoff is greater than about 0.05 Hz. Thus, it is preferable to have the ability to change between a 0.5 and 0.05 Hz cutoff frequency. The high pass filter of FIG. **12** is implemented by a low pass filter configured as an inverting amplifier in a negative feedback circuit to give a net effective high pass transfer function from circuit input to output. The corner frequency of the composite filter can be adjusted by switching in resistor R**2'**. Alternatively, S**1** can be switched at a periodic rate to place a duty cycle on C. Note that the frequency of switching of SI should be fast with respect to the corner frequency of the anti-aliasing low pass filter. The graphs A-D of FIG. **13** further illustrate the performance of the exemplary filter of FIG. **12**. These graphs show normalized amplitude on the vertical axis plotted against frequency on the horizontal axis. FIG. **13**, graph A represents a raw input signal. FIG. **13**, graphs B and C are Bode Plots representing the high and low-pass filter sections. After applying filter responses B & C to input Data A, filtered data D is the result. The HPF cutoff can be 0.5 Hz or some lower value depending on whether R**2'** is switching in or if C is duty cycled.

[0091] Another method to achieve this frequency change is to use digital filters implemented on Microprocessor **512** to reverse the effects of the 0.5 Hz HPF, then implement a digital HPF at a lower cutoff frequency, 0.05 Hz, for example. The response of the 0.5 Hz filter should be known to implement the inverse filter. This response can be measured using microprocessor **512** to trigger the test circuit **906** to create an impulse, H(s). The inverse response is the [1-H(s)] (FIG. **13**, graph E) and this inverse filter can be digitally implemented by methods familiar to those skilled in the art. H'(s) is the frequency response of the new HPF with lower cutoff frequency, nominally 0.05 Hz. The digital filter for H'(s) is digitally generated (F) and applied along with [1-H(s)] (FIG. **13**, graph E), resulting in the frequency response displayed in FIG. **13**, graph G. A high pass filter suitable for use in ECG circuits block **510** can be implemented in full or in part by software that can run on microprocessor **512**.

[0092] FIG. **14** shows how a body worn monitor **100** configured as an ECG monitor can be situated on a patient in at least two different orientations to measure different heart vectors. A primary heart vector is measured by orientation from the patient's right shoulder to the left hip, as shown by position **1401**. An alternative position **1402** can be more suitable where there is injury or where patient anatomy is such that it causes the preferred position **1401** to be less desirable. Also, body worn monitor **100** can be affixed to the side of patient **703** (similar to a measurement made by a conventional ECG "V" lead) or back of a patient **703** (such as where a patient needs to sleep on their stomach) to monitor still other ECG vectors (not shown). In effect, a body worn monitor **100** can be placed to pick a particular vector that can be traversed by the electrodes **109**. For example at least the first three primary heart vectors, i.e. I, II, and III, can be made conveniently available in this manner.

[0093] While illustrated with an internal battery, it is important to note that a body worn physiological monitor **100** can be powered by either an internal power source only, an external power source only, or by an internal or an external power source. An internal power source can be a renewable power source, such as a rechargeable battery.

[0094] Another type of internal power source is a Peltier device operated in reverse, also called a Seebeck device. Seebeck discovered that a conductor generates a voltage when subjected to a temperature gradient. Thermoelectric couples are solid-state devices capable of generating electrical power from a temperature gradient, known as the Seebeck effect. (By contrast, the Peltier effect refers to the situation where electrical energy is converted into a temperature gradient.) A Seebeck device "couple" consists of one N-type and one P-type semiconductor pellet. The temperature differential causes electron flow from hot to cold in the N-type couple and hole flow from hot to cold in the P-type couple. To create an electromotive force (EMF), the following connections are made: On the cold side (i.e. the side that is exposed to room temperature) the pellets are joined and on the hot side (i.e. the patient side), the pellets are connected to a load, such as the computation and communication module **102**. The open circuit voltage of a Seebeck device is given by $V=S\,\Delta T$, in which S is the Seebeck coefficient in volts/° K and ΔT is the temperature difference between the hot and cold sides. It is a challenge today to completely power the computation and communication module **102** from a Seebeck device that is of the same size as the computation and communication module **102**. Presently, a Seebeck device may only provide supplementary power, but as electronics migrate toward lower power and Seebeck coefficients and thermocouple densities improve, a Seebeck device can be a viable long-term power solution for a patient-worn monitor. Other methods of generating energy, such as mechanical (as is used in some wrist watches) and solar, can also be viable methods for providing a renewable self-contained power source for a body worn monitor.

[0095] Turning to analysis routines suitable for use on a body worn monitor, typically, ECG beat picking, such as by using wavelet or Fourier transforms and/or matched filter analysis in the time domain can be computationally expensive. Modeling the QRS pulse as three triangles with alternating polarities creates a rough matched filter for the QRS pulse. Taking the second derivative results in impulse functions at the peaks of the triangles (where the first derivative is discontinuous), and all other points are zero. The second derivative method also makes the convolution with incoming data extremely efficient as most of the multiplies have a 0 as the multiplicand and requires minimal computation. The result can then be integrated twice to produce a matched-filter output, which can be fed into the beat-picking algorithm that provides fiducial marks. Using a second matched filter that is sinusoidal in shape and with appropriate discriminators, the system can provide indications of Life Threatening Arrhythmias (LTA); that is, Asystole, Vfib, and Vtach. While the accuracy of this system is less competitive with a high-end Arrhythmia solutions such as those provided, for example, by Mortara, the filters can be tuned to err toward false positives and upon a positive LTA response, activate transmission of full waveforms.

[0096] Research has also shown that analysis of the R-R portion of the ECG waveform interval statistics can provide a method to predict atrial flutter. Applying this and other low-computational cost methods can allow a body worn monitor device to begin transmitting full waveforms for either clinical or algorithmic analysis by a more powerful engine, when the probability of other arrhythmias is high. Transmitting only

the R-R intervals of ECG waveforms is an example of a lossy data compression method. R-R intervals comprise a string of data and the string of data can also be compressed. Lossless or lossy data compression of the entire waveform can be implemented to save battery life, including not transmitting (or perhaps not even sampling) data between the T and the P wave. Because data compression results in less data to transmit, the power saved may offset the computation cost of the data compression.

[0097] While we have referred often to ECG applications herein, the application of low-intensity computational methods as a power saving measure apply equally well to other types of low power-sensors, including, but not limited to EEG, SPO_2, temperature, and invasive or non-invasive blood pressure measurements. Whether the body-worn medical-grade monitor performs complex analysis or simply compares a single numeric value to a single numeric limit, the device can function in a low-power radio state until a predetermined threshold is exceeded. A body worn monitor can also periodically send data or send data upon external request. Additionally, external devices can send commands to modify the operating parameters and thresholds.

[0098] Turning to other communication matters, it may be that adverse events occur in which no uplink is available. In a case of no uplink (failed communications), the body worn monitor can buffer time-stamped waveforms corresponding to any adverse events. The buffers can also store waveforms for later analysis in which this storage is triggered by the patient when the patient recognizes a condition, such as chest pain. In the case of an alarm that occurs when there is no uplink, alarms can be configured to be latched until confirmed by a clinician. Preferably, non-continuous data are marked (time stamp, sample number) to allow correlation of non-continuous data with continuous data and data are also marked to indicate when an alarm was initiated for later data analysis, including algorithm performance analysis.

[0099] In those instances in which many body worn monitor devices are used in close proximity to one another, there can be concern that the reports from one body worn monitor might be interchanged with reports from another body worn monitor. The body worn monitor presented herein, can be configured with a patient context (i.e. name, room number, patient ID, age, etc) and can maintain that context for as long as the monitor is connected to the patient to avoid such problems. The body worn monitor can determine the status of its connection to the patient via a continuous vital signs monitor, pressure, temperature, galvanic response, or similar input. Upon detection of a loss of connection with a patient, the device can, depending upon different variable settings, either erase the patient context or when re-connected to the patient, require the care giver to confirm the patient context. When the body worn monitor is initially powered up or connected to a patient, it can have a time holdoff for alarms to prevent false alarms (e.g. low heart rate, lead-fail detection) while the system stabilizes.

[0100] Regarding firmware updates, where there are large numbers of body worn monitors in a hospital, it can be problematic to keep them all updated with the latest version of firmware. One solution to this problem is to provide a wireless update ability for downloading and installing new firmware and/or configurations into all of the body worn monitors.

[0101] While the present invention has been particularly shown and described with reference to the preferred mode as illustrated in the drawings, it will be understood by one skilled in the art that various changes in detail may be effected therein without departing from the spirit and scope of the invention as defined by the following claims. It is further understood that several aspects of the invention, including, but not limited to, defibrillation protection resistors, pacer detect circuit disabling, methods for ECG signal high pass filtering, and various other low power modes are not limited to body worn monitors, and can be used in ECG monitors of any type.

We claim:

1. A body worn patient monitoring device comprising:

at least one disposable module including a plurality of electrical connections, the electrical connections couplable to a skin surface to measure physiological signals, the at least one disposable module including a disposable module connector;

at least one internal or external power source to power the body worn patient monitoring device; and

at least one communication-computation module, having a communication-computation module connector to receive physiological signals from the at least one disposable module via said disposable module connector, the communication-computation module including at least one microprocessor to actively monitor the patient and to perform a real-time physiological analysis of the physiological signals and a radio circuit to communicate an unprocessed physiological signal or a result of the physiological analysis at a predetermined time or on the occurrence of a predetermined event, via a radio transmission to a remote radio receiver, wherein the at least one disposable module is mechanically and electrically coupled directly to the at least one communication-computation module and the body worn patient monitoring device including the at least one disposable module and the at least one communication-computation module is directly non-permanently affixed to the skin surface of the patient.

2. The body worn device of claim **1**, wherein the plurality of electrical connections to the body comprise at least one of direct electrical connections to the body and indirect electrical connections to the body.

3. The body worn device of claim **2**, wherein the indirect electrical connections to the body comprise capacitive connections to the body.

4. The body worn device of claim **1**, wherein the body worn patient monitoring device comprises an ECG monitor and at least two of the electrical connections are ECG electrodes.

5. The body worn device of claim **4**, wherein the ECG electrodes comprise a material screened onto a flexible substrate.

6. The body worn device of claim **5**, further comprising at least one series current-limiting resistor to protect the communication-computation module during a patient defibrillation event.

7. The body worn device of claim **6**, wherein the least one series current-limiting resistor comprises a resistor screened on the flexible substrate.

8. The body worn device of claim **7**, wherein the mechanical interface from the at least one series current-limiting resistor to the ECG electrode includes a filleted edge.

9. The body worn device of claim **7**, wherein the mechanical interface from the at least one series current-limiting resistor to the ECG electrode comprises overlapped layers.

10. The body worn device of claim **9**, wherein the overlapped layers comprise a carbon resistive layer screened over a conductive surface, the carbon resistive layer having substantially the same shape as the conductive surface.

11. The body worn device of claim **6**, further comprising an insulating material overlaying the at least one series current-limiting resistor to prevent arcing.

12. The body worn device of claim **5**, wherein the ECG electrodes are formed substantially in the shape of an annulus.

13. The body worn device of claim **12**, wherein the annulus comprises a conductive ink.

14. The body worn device of claim **5**, wherein the substrate is shaped to allow placement on the patient to monitor at least one of a set of standard ECG vectors while simultaneously reducing motion and muscle artifact in the corresponding ECG vector signal.

15. The body worn device of claim **1**, wherein the at least one power source is a renewable power source internal to the body worn device.

16. The body worn device of claim **1**, wherein the at least one power source comprises a rechargeable battery or a one time use battery.

17. The body worn device of claim **1**, wherein the at least one power source is a battery contained within said disposable module.

18. The body worn device of claim **1**, wherein the at least one power source is a Seebeck device.

19. The body worn device of claim **1**, wherein one of the electrical connections is a reference electrode that can be used to improve common mode rejection (CMR).

20. The body worn device of claim **1**, further comprising a virtual electrode as a reference electrode to improve CMR.

21. The body worn device of claim **20**, wherein the virtual electrode is an electrode situated near the skin of the patient, but not directly connected to the skin.

22. The body worn device of claim **20**, wherein the virtual electrode comprises a capacitive coupling of a body of the communication-computation module to the skin surface of the patient to reduce power line frequency interference.

23. The body worn device of claim **20**, including a reference electrode switch for selectively choosing between using the virtual electrode as the reference electrode and a directly connected electrode as the reference electrode and wherein when the reference electrode switch selects the virtual electrode, the directly connected electrode can be used as an additional ECG electrode.

24. The body worn device of claim **20**, wherein the reference electrode is a passive electrical connection or the reference electrode is actively driven.

25. The body worn device of claim **1**, wherein the communication-computation module includes a pacer detection circuit.

26. The body worn device of claim **25**, wherein the pacer detection circuit generates a microprocessor interrupt to inform the microprocessor that a pacer event occurred.

27. The body worn device of claim **26**, wherein the microprocessor interrupt is used to mark a corresponding physiological signal in time as related to a pacer event.

28. The body worn device of claim **26**, wherein the device automatically determines if a patient has a pacemaker and only enables the pacer detect circuit when a pacemaker is present.

29. The body worn device of claim **26**, wherein the device is configured by an external input to enable or disable the pacer detect circuit.

30. The body worn device of claim **1**, wherein the body worn device includes circuit protection to allow the device to survive multiple defibrillation cycles of at least 360 joules.

31. The body worn device of claim **30**, wherein the circuit protection comprises a gas discharge tube or a plurality of diodes to clamp or limit the signals from the electrical connections.

32. The body worn device of claim **30**, wherein a plurality of components of the circuit protection are distributed between the disposable module and the communication-computation module.

33. The body worn device of claim **1**, further comprising a high pass filter with a selectable corner frequency to filter the physiological signals.

34. The body worn device of claim **33**, wherein the corner frequency is selected by a switch selectable resistance.

35. The body worn device of claim **33**, wherein the corner frequency is selected by one or more switching capacitors switched a rate higher than the corner frequency of a low pass anti-aliasing filter.

36. The body worn device of claim **33**, wherein the high pass filter is implemented in software running on the microprocessor.

37. The body worn device of claim **1**, wherein the body worn device self checks a pacer detection circuit by injecting a simulated pacer pulse into a front end amplifier to stimulate the pacer detection circuit by simulating the presence of a patient's pace maker.

38. The body worn device of claim **1**, wherein the communication-computation module includes circuit components to detect failure of contact of one or more of the electrical connections with the skin surface of the patient.

39. The body worn device of claim **1**, wherein the communication-computation module is protected from external high energy signals by electro-surgical isolation suppression circuits.

40. The body worn device of claim **1**, wherein the microprocessor automatically enters a sleep mode during a conversion cycle of an analog to digital converter (ADC) to minimize noise pickup from digital circuits on the body worn device.

41. The body worn device of claim **1**, wherein an algorithm running on a microprocessor in the body worn device causes the body worn device to enter a low power mode that disables at least one circuit of the body worn device, from the end of a "T wave" at the end of one heart beat to the beginning of a "P wave" at the beginning of the next heart beat, to save power.

42. The body worn device of claim **4**, including an ESIS filter having a low enough corner frequency such that the energy from a pacer pulse is recorded by at least one sample, even though the pacer pulse itself is of small duration compared to the sample rate and the pacer pulse occurs between samples.

43. The body worn device of claim **1**, wherein neon bulbs connected from the physiological sensors to an electronics common (ground) protect one or more internal circuits of the communication-computation module from a defibrillation pulse.

44. The body worn device of claim **1**, wherein a plurality of diodes disposed between the physiological sensors and an

electronics common (ground) protect one or more internal circuits of the communication-computation module from a defibrillation pulse.

45. A method of providing high voltage circuit protection for a body worn monitor comprising the steps of:

providing a substrate that supports one or more electrical connections to a patient's body;

determining a print pattern and thickness of a first material having a first resistivity to be printed on the substrate;

determining a print pattern and thickness of a second material having a second resistivity to be printed on the substrate;

printing the first material onto the substrate; and

printing the second material onto the substrate wherein at least part of the second the material overlays the first material.

46. The method of claim **45**, wherein both of the steps of determining a print pattern and thickness of both the first and second materials comprise the additional steps of determining a print pattern and thickness of both the first and second materials, including a filleted section.

47. The method of claim **45**, wherein both of the steps of determining a print pattern and thickness of both the first and second materials comprise the further steps of determining a print pattern and thickness of both the first and second materials to achieve a total resistance value.

48. The method of claim **45**, wherein both of the steps of determining a print pattern and thickness of both the first and second materials comprise the further steps of determining a print pattern and thickness of both the first and second materials to achieve a spacing between two or more electrical traces of the print pattern, and applying an insulating layer after the step of printing of the second material.

49. An ECG monitor comprising:

a plurality of electrical connections including at least one electrode, the electrical connections being couplable to a skin surface to measure patient heartbeat signals;

at least one internal or external power source to power the ECG monitor;

at least one current-limiting defibrillation protection resistor, said at least one current-limiting defibrillation protection resistor comprising a resistor screened onto a substrate; and

an ECG electronics module, to receive and process patient heartbeat signals from said plurality of electrical connections, wherein said at least one current-limiting defibrillation protection resistor is electrically disposed between at least one of said plurality of electrical connections and said ECG electronics module.

50. The ECG monitor of claim **49**, wherein said at least one current-limiting defibrillation protection resistor comprises a resistor screened onto a flexible substrate.

51. The ECG monitor of claim **49**, wherein a mechanical interface is defined from said at least one series current-limiting resistor to said at least one ECG electrode, said mechanical interface including a filleted edge.

52. The ECG monitor of claim **49**, wherein a mechanical interface is defined from the at least one series current-limiting resistor to said at least one ECG electrode, said mechanical interface including a plurality of overlapped layers.

53. The ECG monitor of claim **52**, wherein said plurality of overlapped layers comprise a carbon resistive layer screened over a conductive surface, the carbon resistive layer having substantially the same shape as said conductive surface.

54. An ECG monitor comprising:

a plurality of electrical connections, said plurality of electrical connections being couplable to a skin surface to measure patient heartbeat signals;

at least one internal or external power source to power the ECG monitor; and

an ECG electronics module to receive and process patient heartbeat signals from said plurality of electrical connections and including a pacer detect circuit to detect the presence or absence of a pacemaker, said ECG electronics module drawing power as an electrical load on said power source wherein said pacer detect circuit, upon detection of the absence of a pacemaker signal in a patient being monitored by the ECG monitor, causes said ECG electronics module to disable said pacer detect circuit in order to reduce said electrical load on said power source.

55. The ECG monitor of claim **54**, wherein said power source is a battery.

56. A method to improve ECG signal high pass filtering including the steps of:

providing an ECG monitor having a programmed microprocessor and a plurality of electrical connections to measure patient heartbeat signals;

filtering said measured heartbeat signals with an analog high pass filter having a analog high pass cutoff frequency;

removing the effects of said analog high pass filter with a digital inverse filter algorithm resulting in substantially unfiltered heartbeat signals;

filtering said substantially unfiltered heartbeat signals digitally using a digital filter having a digital high pass filter cutoff frequency lower than said analog cutoff frequency.

57. The method of claim **56**, wherein the step of filtering said measured heartbeat signals with an analog high pass filter comprises the step of filtering said measured physiological signals with an analog high pass filter having a 0.5 Hz analog high pass cutoff frequency, and the step of filtering said substantially unfiltered heartbeat signals digitally comprises the step of filtering said substantially unfiltered heartbeat signals digitally using a digital filter having a digital 0.05 Hz high pass filter cutoff frequency.

58. An ECG monitor comprising:

a plurality of electrical connections, said electrical connections being couplable to a skin surface to measure patient heartbeat signals;

at least one internal or external power source to power the ECG monitor; and

an ECG electronics module to receive and process heartbeat signals from said plurality of electrical connections, said ECG electronics module drawing power as an electrical load on said power source, said ECG electronics module including a microprocessor to process heartbeat signals, wherein an algorithm running on said microprocessor causes the ECG monitor to enter a low power mode that disables at least one circuit of the ECG electronics module, from the end of a "T wave" at the end of one heartbeat to the beginning of a "P wave" at the beginning of the next heartbeat, in order to reduce said electrical load on said power source.

* * * * *

Exhibit C

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(54) **ELECTRODE STRUCTURE AND HEART RATE MEASURING ARRANGEMENT**

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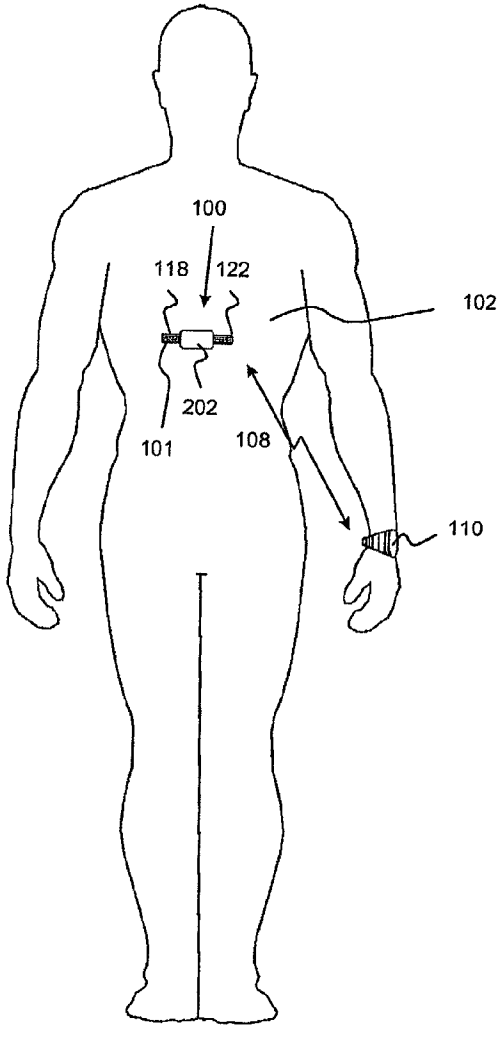
(52) **U.S. Cl.** **600/391**; 600/393

(57) **ABSTRACT**

The invention relates to an electrode structure and a heart rate measuring arrangement for measuring an ECG signal on the skin of a person's chest. The electrode structure (**100**) comprises a band-like component (**101**) that is fitted against the skin (**102**) of the person's chest and that is made of soft and flexible material that follows the skin closely. At the ends of the electrode structure (**100**) there are electrodes (**118, 122**). The inner surface (**116**) of the electrode structure is an adhesive surface for attaching the electrode structure (**100**) on the skin (**102**) of the person's chest.



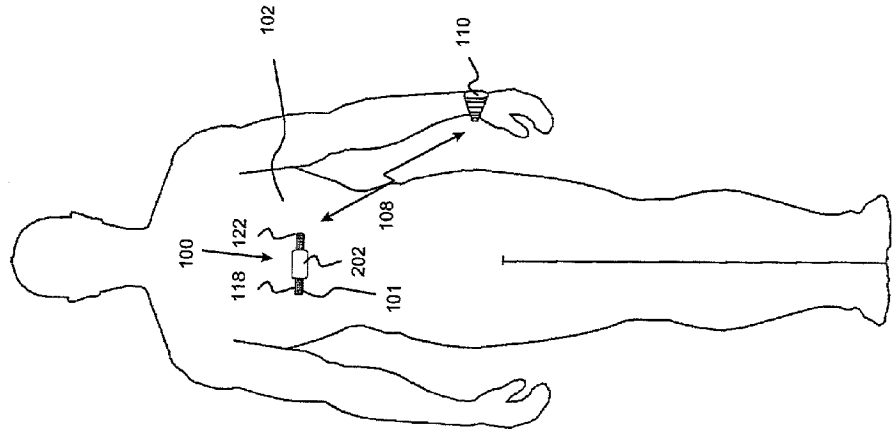


FIG.2

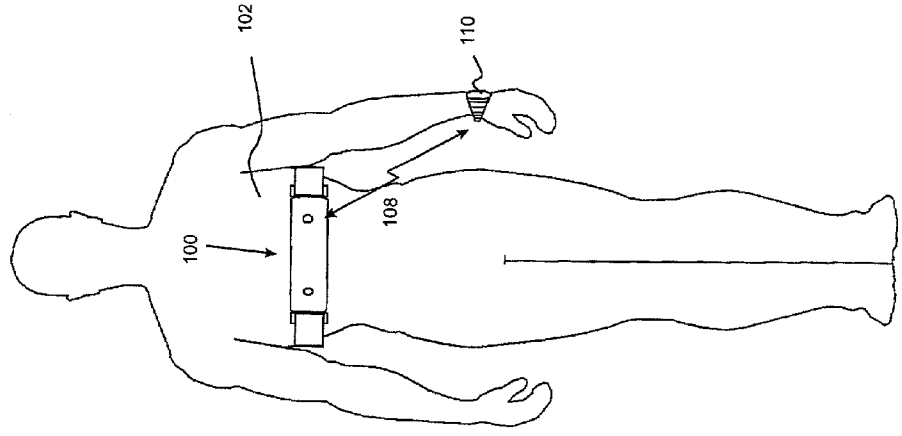


FIG.1

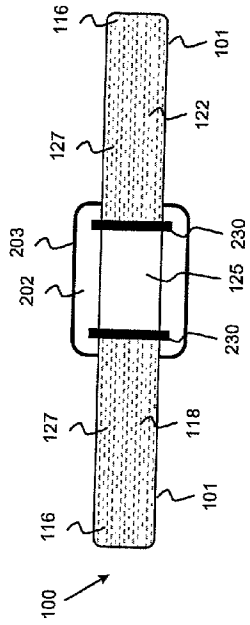


FIG.7

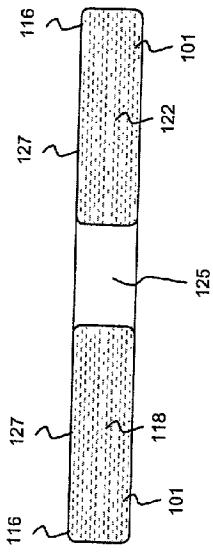


FIG.8

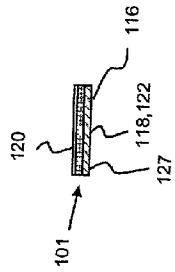


FIG.9

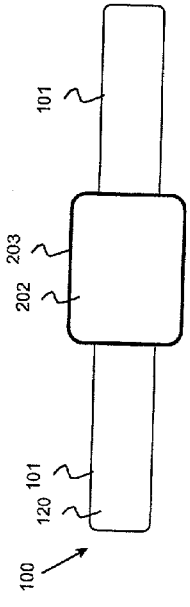


FIG.3

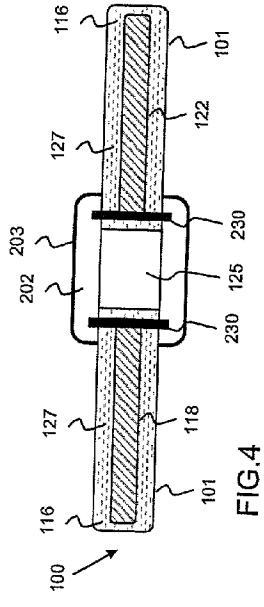


FIG.4

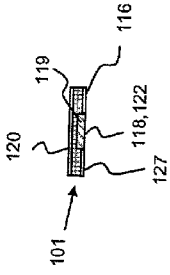


FIG.5

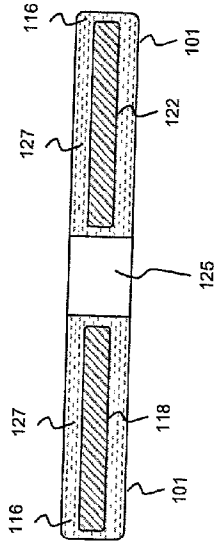


FIG.6

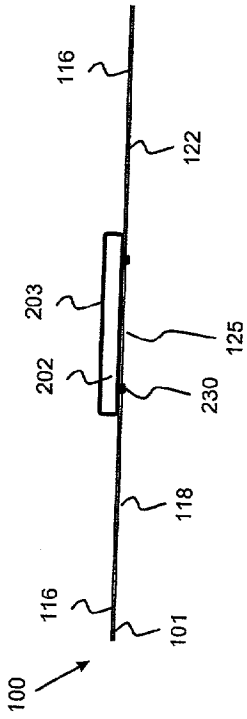


FIG.10

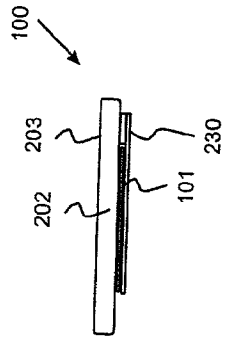


FIG.11

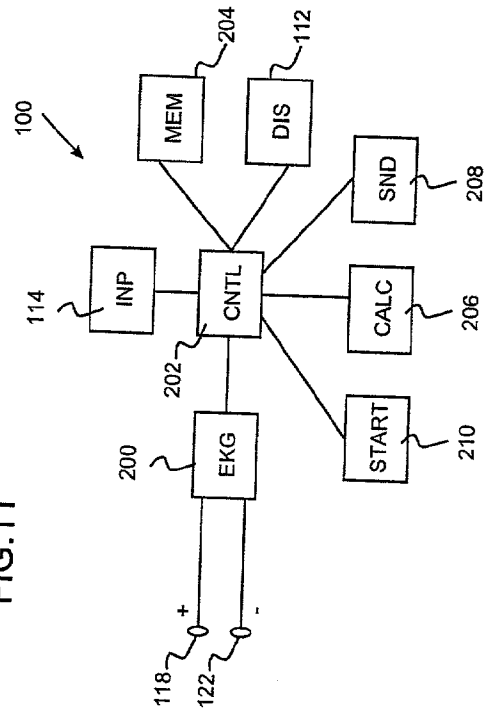


FIG.12

ELECTRODE STRUCTURE AND HEART RATE MEASURING ARRANGEMENT

FIELD OF THE INVENTION

[0001] The invention is applied to a device for non-invasive measurement of heart rate information, in particular to a heart rate monitor used in connection with exercise and sports.

BACKGROUND OF THE INVENTION

[0002] The measurement of heart beat frequency is an interesting field of application in connection with exercise. On the basis of the heart beat frequency, i.e. the heart rate, it is possible to obtain information e.g. on a person's stress level, recovery and development of physical condition, and consequently the proportion of training exercises and rest can be monitored and planned better.

[0003] The heart rate is measured on a person's skin on the basis of an electrocardiographic (ECG) signal generated by a heart beat. Additional information on ECG is available in the following publication by Guyton, Arthur, C., *Human Physiology and Mechanisms of Disease,* third edition, W. B. Saunders Company, 1982, ISBN 4-7557-0072-8, Chapter 13: The Electrocardiogram, which is incorporated herein as reference. The electrocardiographic signal is an electromagnetic signal originating from a heart beat, which is detected on the body of a person to be measured. The signal is measured by means of electrodes, which are in contact with the body at least at two points. By a polarization vector, the electrode that is located closest to the heart often acts in practice as the actual measuring electrode, while the other electrode serves as ground potential, to which the voltage measured by the measuring electrode is compared as a function of time.

[0004] The heart rate monitor electrodes to be placed on the chest are arranged in a known manner in a belt-like structure, i.e. a so-called electrode belt. The electrode belt is thus a ring-shaped attachment means that goes round the whole chest and can be tightened round the human chest. A structure of this kind is shown in **FIG. 1**. The electrode belts are known to have structures that comprise an electronic unit in the middle of the belt, with an electrode on both sides. The electrodes measure the electric pulse transmitted by the heart and transmit the measurement results to the electronic unit through an interface connecting the electrode and the electronic unit. The components included in the electrode belt, such as the electronic unit and the electrodes, are generally coated with plastic or rubber in order to protect the components against moisture, for instance. Depending on the structure of the electrode belt, the electronic unit often also comprises means for transmitting an electric pulse as an analog burst to a receiver and display unit worn on the wrist, for instance. Alternatively, the electrode belt itself may comprise the means for storing and displaying the electric pulses.

[0005] In general, the electrode belts have a structure in which the rubber or plastic support structure covering the components of the electrode belt is relatively rigid. These electrode belts are, in general, poorly suited for long-term, continuous use, and they chafe the skin easily. The belt-like structure of the electrode belt also limits its optimal positioning substantially at the heart with persons having large quantities of muscular or other tissue in the chest area. Also slim adults and children have troubles in wearing the rigid electrode belt, because it does not bend sufficiently to follow the contours of a human body with a narrow chest. In some prior art solutions, the problem is approached such that the plastic support structure between the electronic unit and the electrode is pleated, whereby the electrode belt bends immediately outside the electronic unit. However, this solution only reduces rigidity in bending the electrode belt, because the electrode belt is still ring-shaped and attachable round the chest.

[0006] The prior art solution has a serious drawback: it is difficult to fit the rigid electrode belt optimally round the chest to achieve the best measurement result, in particular in long-term, continuous use, when the electrode belt also chafes the skin easily.

BRIEF DESCRIPTION OF THE INVENTION

[0007] The object of the invention is to provide an improved electrode structure and heart rate measuring arrangement for measuring an electrical heart beat signal on a human body such that the above problems can be solved. This is achieved with the following electrode structure for measuring an ECG signal on the chest of a person. The electrode structure comprises a band-like component having an inner surface to be placed against the skin of the person's chest and an outer surface opposite thereto, and which electrode structure comprises a first electrode at a first end and a second electrode at a second end of the electrode structure, and the inner surface of the electrode structure is an adhesive surface for attaching the electrode structure to the skin of the person's chest, and the electrode structure is arranged to measure a potential difference between the first and the second electrodes caused by the ECG signal.

[0008] The invention also relates to a heart rate measuring arrangement for measuring the ECG signal on the skin of a person's chest. The heart rate measuring arrangement comprises an electrode structure placed on a person's chest and a wrist-worn receiver unit, the electrode structure comprising a band-like component having an inner surface against the skin of the person's chest and an outer surface, opposite thereto, and which electrode structure comprises a first electrode at a first end and a second electrode at a second end of the electrode structure, the inner surface of the electrode structure being an adhesive surface for attaching the electrode structure to the skin of the person's chest, and the electrode structure being arranged to measure a potential difference between the first and the second electrodes caused by the ECG signal, the electrode structure further comprising ECG processing means communicating with the electrodes for measuring the potential difference between the first and the second electrodes caused by the ECG signal and for producing heart rate information on the basis of the measured potential difference, and the electrode structure further comprising a transmitter for transmitting the heart rate information to the wrist-worn receiver which comprises a receiver for receiving the heart rate information transmitted from the electrode structure, the wrist-worn receiver further comprising a display for presenting the heart rate information.

[0009] The preferred embodiments of the invention are disclosed in the dependent claims.

[0010] In the solution of the invention, it is intended that the electrode structure is placed on the skin of the user's chest. In one embodiment, the band-like component of the electrode structure is of flexible, soft material that fits the skin closely, and as a consequence it is comfortable and inconspicuous to wear and does not chafe the skin, and hence it is well suited for long-term use in ECG measuring. In one embodiment the band-like component of the electrode belt is continuous, in which both electrodes and their attachment means are integrated. The band-like component is disposable and economical to manufacture. In terms of design, it is a plaster-like sticker, for instance.

[0011] The electrode structure has a first electrode at a first end and a second electrode at a second end. The first and the second electrodes of the electrode structure are electrically separated from one another in order to enable the measurement of the potential difference between the electrodes. For optimal measurement of the heart rate signal, the first and the second electrodes should be located sufficiently far apart from one another so as to detect an electric ECG signal generated by a heart beat. The electrodes are thus advantageously placed at the ends of the electrode structure. Naturally, there may be more than said two electrodes.

[0012] According to a preferred embodiment, the inner surface of the electrode structure is an adhesive surface for attaching the electrode structure on the skin of the person's chest. An advantageous manner to implement the adhesive surface and the electrodes is the embodiment, in which the electrodes located at the ends of the band-like component of the electrode structure are made of electrically conductive adhesive. Hence, the adhesive attaches the electrode structure on the skin of the person's chest. In a second embodiment the first electrode and the second electrode of the electrode structure consist of an electrically conductive membrane at both ends of the electrode structure, at the electrode. On the inner surface of the membrane, which is placed against the person's skin there is an electrically conductive adhesive. The adhesive is preferably an electrically conductive glue. Further, a third manner to implement the electrodes and the adhesive surface is an embodiment, in which the first electrode and the second electrode of the electrode structure consist of an electrically conductive membrane at both ends of the electrode structure, at the electrode, and the electrodes at both ends of the electrode structure are narrower than the band-like component. Around the electrodes, on the outer edges of the band, on the inner surface thereof, there is an adhesive, with which the electrode structure is attached to the person's skin. In this case, the adhesive need not be electrically conductive. Because the inner surface of the electrode structure is that portion of the electrode structure which is against the person's skin, the electrodes are preferably located on the inner surface of the band. The electrode structure can also be designed such that the electrodes are partly or completely located on both the inner surface and the outer surface of the band. Further, the electrode structure can be designed such that the electrodes are located on the inner surface of the band, but they have interfaces also on the outer surface of the band.

[0013] The electrode structure also comprises an electronic unit communicating with the electrodes. The electronic unit is an electronic component attached to the band-like part of the electrode structure with one or more gripping means. The electrodes of the electrode structure communicate with the electronic unit. The electronic unit comprises ECG processing means, by which the potential difference caused by the ECG signal between the first and the second electrodes is measured, and an estimate for detected heart beat time instants is formed from the heart rate signals measured by the electrodes, and further the heart beat rate is calculated on the basis of the detected heart beat time instants. The electronic unit also comprises a transmitter for transmitting heart rate information to a wrist-worn receiver, which comprises a receiver for receiving the heart rate information transmitted from the electrode structure, and a display for presenting the heart rate information.

[0014] The wrist-worn receiver is located in a watch-like device that the user wears on his wrist, such as a heart rate monitor or a wrist computer. Transmission of information between the electrode structure and the heart rate monitor is thus carried out in known manners, for example through a connecting line, optically or electromagnetically. In the embodiment in question, the display for presenting the heart rate information is also preferably located in the wrist-worn receiver.

[0015] The electronic unit is preferably arranged in a casing which comprises one or more gripping means for attaching the electronic unit to the stap-like component of the electrode structure. The gripping means are most preferably located on that surface of the electronic unit casing which is against the person's skin. The preferable structures of the gripping means include attachment slots, a pivoted, clamping clip, or the like, that are in the central unit casing. The gripping means or the central unit casing comprises conductive connecting means, through which the ECG signal measured with the electrodes is applied from the electrodes to the electronic unit.

[0016] The invention also has an advantage that the electrode structure is inconspicuous, comfortable and well suited for long-term use as compared with the known solutions.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] In the following, the invention will be described in greater detail with reference to the attached drawings, wherein

[0018] **FIG. 1** shows a prior art transmitter electrode belt placed on a person's chest and a receiver unit worn on a wrist.

[0019] **FIG. 2** shows a heart rate measuring arrangement placed on a person's chest according to one embodiment of the invention,

[0020] **FIG. 3** shows an outer surface of one embodiment of an electrode structure according to the invention.

[0021] **FIG. 4** shows an inner surface of the electrode structure of **FIG. 3**,

[0022] **FIG. 5** shows a cross section of the electrode structure of **FIG. 3**,

[0023] **FIG. 6** shows a band-like part of the electrode structure of **FIG. 3**,

[0024] **FIG. 7** shows an inner surface of a second embodiment of the electrode structure according to the invention,

[0025] **FIG. 8** shows a band-like part of the electrode structure of **FIG. 7**,

[0026] **FIG. 9** is a cross section of the electrode structure of **FIG. 7**, seen at the electrode,

[0027] **FIG. 10** is a side view of an embodiment of the electrode structure according to the invention,

[0028] **FIG. 11** is a cross section of one embodiment of a central unit of the electrode structure according to the invention, and

[0029] **FIG. 12** shows a device arrangement for providing a heart rate according to one embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0030] In the following the invention will be described by means of preferable embodiments, with reference to the attached drawings **2** to **12**.

[0031] **FIG. 2** shows a person whose heart rate is measured by means of an electrode structure **100** placed on the chest **102**. The heart rate is measured by means of two or more electrodes **118**, **122** in the electrode structure **100**, between which electrodes is formed a measurable potential difference as the heart beats.

[0032] The presented electrode structure **100** comprises a band-like component **101**. It is preferably a continuous band **101** having an inner surface **116** against the skin of the person's chest and an outer surface **120** opposite thereto. At a first end of the electrode structure **100** there is a first electrode **118** and at a second end of the electrode structure **100** there is a second electrode **122**. The first electrode **118** and the second electrode **122** of the electrode structure are electrically separated from one another by a separating zone **125** between the electrodes in the band **101** in order to enable the measurement of the potential difference between the electrodes. A measurable potential difference is thus produced between the first electrode **118** and the second electrode **122**, i.e. an ECG signal which is measured with the electrode structure **100**.

[0033] The inner surface **116** of the electrode structure is an adhesive surface, by which the electrode structure **100** is attached to the skin **102** of the person's chest. The band **101** of the electrode structure **100** is of flexible, soft material that fits the skin closely. For instance, the band **101** can be of plastic, textile fibre, a combination thereof or the like. Preferably, the band **101** is disposable.

[0034] According to one preferred embodiment, as in FIGS. **7** to **9**, the electrodes **118**, **122** of the electrode structure **100** are provided of electrically conductive adhesive **127** on the inner surface **116** of the band **101**, at both ends of the band **101**. The adhesive **127** is preferably an electrically conductive glue, such as electrically conductive Solgel or a conductive silicone glue.

[0035] According to a second embodiment, as in FIGS. **3** to **6**, the electrodes **118**, **122** of the electrode structure **100** consist of a membrane **119** that is located at both ends of the electrode structure **100**, at the electrode **118**, **122**, and is made of metal, electrically conductive plastic or a similar conductive material. The electrodes **118**, **122** at both ends of the electrode structure **100** can be equal or narrower in width to the band-like component **101**. The membrane **119** can thus come into contact with the person's skin surface **102** or on the inner surface **116** of the membrane **119** which is against the person's skin there can be an electrically conductive adhesive **127**. The adhesive **127** is preferably a conductive glue, such as conductive Solgel or a conductive silicone glue. If the electrode **118**, **122** is narrower than the band-like component **101**, it is possible to use a non-conductive adhesive **127** on outer edges of the band **101**, on the inner surfaces thereof, outside the electrodes **118**, **122**.

[0036] Because the inner surface **116** of the electrode structure **100** is the portion which is against the person's skin, the electrodes **118**, **122** are preferably located on the inner surface **116** of the band **101**. The electrode structure **100** can also be designed such that the electrodes **118** and **122** are partly or completely on both the inner surface **116** and the outer surface **120** of the band. Further, the electrode structure **100** can be designed such that the electrodes **118**, **122** are located on the inner surface **116** of the band, but they have interfaces also on the top surface **120** of the band **101**.

[0037] According to **FIGS. 2**, **3**, **4**, **7**, **10** and **11**, the electrode structure **100** also comprises a central unit **202** that communicates with the electrodes **118**, **122**. The central unit **202** is a separate electronic part which is attached to the band-like part **101** of the electrode structure **100** with one or more gripping means **230**. The electronic unit **202** is arranged in a casing **203** which comprises one or more gripping means **230** for attaching the electronic unit **202** to the band-like component **101** of the electrode structure **100**. The gripping means **230** are preferably located on that surface of the electronic unit **202** casing **203** which is against the person's skin.

[0038] The electrodes of the electrode structure **100** have an electrically conductive connection to the central unit **202**. The connection is preferably implemented such that the gripping means **230** provide an electrical coupling between the electrodes **118**, **122** and the electronic unit **202**. The structures of the gripping means **230** include attachment slots, a pivoted, clamping clip, or the like, that are in the central unit casing. The gripping means **230** or the lower surface of the central unit casing **202** comprise conductive connecting means, through which the ECG signal measured with the electrodes **118**, **122** is applied from the electrodes **118**, **122** to the central unit **202**.

[0039] The central unit **202** comprises ECG processing means, by which the potential difference between the first and the second electrodes, caused by the ECG signal, is measured, and heart rate information, comprising a heart rate pulse, detection and calculation of heart beat intervals or a heart rate frequency, i.e. the heart rate, is formed from the heart rate signals measured by the electrodes. The central unit **202** further comprises a transmitter **208** for transmitting the heart rate information to a wrist-worn receiver **110** which comprises a receiver for receiving the heart rate information transmitted from the central unit **202**, and a display **112** for presenting the heart rate information to the user.

[0040] The wrist-worn receiver **110** is located in a watch-like device worn on the wrist, such as a heart rate monitor or a wrist computer. Transmission **108** of information between the electrode structure **100** and the heart rate monitor is thus carried out in known manners, for example through a connecting line, optically or electromagnetically.

In the embodiment in question, the display **112** for presenting the heart rate information is also preferably located in the wrist-worn receiver **110**.

[**0041**] Preferably, the ECG signal to be measured is processed, i.e. filtered, amplified and detected, in the electrode structure **100** by using known methods such that the heart beat can be detected from the ECG signal in order to be transmitted to the receiver unit **110**. In the heart beat detection the electrode structure **100** measures the inter-electrode potential difference or voltage. The heart rate detection is based, for instance, on a QRS complex detected from the heart signal, where the letters Q, R and S refer to the potential phases in the electric signal caused by the electric activation of the heart. In one embodiment the detection of QRS can be performed by means of an adapted filter, whereby a model complex is compared with the measured QRS complex in the electrode structure and if the comparison exceeds a given threshold value, the measured complex is accepted as the heart beat.

[**0042**] The heart rate information measured by the electrode structure **100** is conveyed telemetrically **108** to the wrist-worn, watch-like receiver unit **110**, such as heart rate monitor, wrist computer or the like. The electrode structure **100** comprises a transmitter for transmitting the heart rate information to the receiver unit **110**, which in turn comprises a receiver for receiving the information. For instance, in the case of telemetric, inductive transmission the transmitter and the receiver comprise a coil, whereby the transmission is performed in one or more magnetic pulses per each heart beat. Instead of the magnetic pulse transmission **108**, the heart rate signal information measured by the electrode structure **100** can be conveyed to the receiver unit **110**, for instance, optically, as an RF transmission, by means of a connecting line or in any other known manner.

[**0043**] In one embodiment the receiver unit **110** comprises feeding means **114** for giving commands to the equipment. The commands may include, for instance, commands to start/end measuring the heart rate, to set heart rate limits, to activate a light source, or other corresponding functions comprised by the heart rate monitors. It is clear that the necessary commands can be conveyed to the electrode structure correspondingly using the connection **108** as described in conjunction with the transmission of the heart rate information from the electrode structure **100** to the receiver unit **110**. In one embodiment the receiver unit **110** comprises a display **112** for presenting the produced heart rate information. The heart rate information refers here to information produced from heart beat frequency or information relating to exercise through heart beat, such as heart rate/minute, heart rate variance, set heart rate limits or duration of exercise within a given heart rate range.

[**0044**] The strength of the ECG signal on human skin varies mainly on a vector, whose maximum value is attained at the starting point of the vector, at the right shoulder, and the minimum value at the final point of the vector, in the left heel. Generally, the maximum ECG signal of a human being can be measured by placing the electrodes at the end points of said vector.

[**0045**] **FIG. 12** shows a structure of a device solution according to one preferred embodiment of the invention, in which all structures and functions required by the heart rate measuring, processing and presenting are placed in the electrode structure **100** on the skin **102** of the chest. An ECG signal is measured on the user's skin with the electrode structure and in particular the related electrodes **118**, **122**, and the signals are conveyed to an ECG processing unit **200**. In the ECG processing unit **200** the ECG signal is subjected to necessary signal processing operations such as filtering and amplifying. In the processing unit **200**, the heart rate is further detected from the ECG signal, for instance, by detecting an R peak of the QRS complex to be the strongest in the signal or by detecting a timing point of the QRS complex by means of an adapted filter. The provided heart rate indications are conveyed to a central unit **202**, which coordinates the operation of the electrode structure **100**, and the heart rate frequency can be calculated from said heart rate indications. On the basis of the heart beat frequency, i.e. heart rate, it is possible to form other calculated variables, i.e. heart rate information, in a calculating unit **206** which communicates with the central unit **202**. The heart rate information refers here to heart rate frequency, heart rate variance, heart rate change rate, heart rate limit or any corresponding variable. The electrode structure **100** acting as a heart rate monitor further comprises feeding means **114** for entering feeding data, such as an indication of the starting and ending moment of the heart rate measurement. The feeding means **114** can be implemented, for instance, by push buttons, touch-sensitive display, voice control or the like. The electrode structure **100** further comprises a memory **204**, consisting of a short-term RAM memory for storing the heart rate information and the like, and a ROM memory intended for storing the necessary programs.

[**0046**] The means needed in the device parts, e.g. in the central unit **202**, the calculating unit **206** and the control unit, are preferably implemented by means of software with a general-purpose microprocessor, but different equipment implementations are also possible, for instance, a circuit constructed of separate logic components, or one or more ASICs (Application Specific Integrated Circuit).

[**0047**] Even though the invention is described above with reference to the examples of the attached drawings, it is apparent that the invention is not restricted thereto but it can be modified in a variety of ways within the scope of the inventive idea disclosed in the accompanying claims.

1. An electrode structure for measuring an ECG signal on the skin of a person's chest, wherein

the electrode structure comprises a band-like component having

an inner surface to be placed against the skin of the person's chest and an outer surface opposite thereto, and

which electrode structure comprises a first electrode at a first end and a second electrode at a second end of the electrode structure,

the inner surface of the electrode structure is an adhesive surface for attaching the electrode structure to the skin of the person's chest, and

the electrode structure is arranged to measure a potential difference between the first and the second electrodes caused by the ECG signal.

2. An electrode structure as claimed in claim 1, wherein the band-like component of the electrode structure is a continuous band made of flexible and soft material that fits the skin closely.

3. An electrode structure as claimed in claim 1, wherein the first electrode and the second electrode of the electrode structure are electrically separated from one another.

4. An electrode structure as claimed in claim 1, wherein the electrodes of the electrode structure consist of an electrically conductive adhesive.

5. An electrode structure as claimed in claim 1, wherein the first electrode and the second electrode of the electrode structure consist of a conductive membrane located at both ends of the electrode structure, at the electrode.

6. An electrode structure as claimed in claim 5, wherein the width of the electrode at both ends of the electrode structure is less than the width of the band-like component.

7. An electrode structure as claimed in claim 5, wherein, at the electrode, on the inner surface to be placed against the person's skin there is an electrically conductive adhesive.

8. An electrode structure as claimed in claim 4, wherein the adhesive is an electrically conductive glue.

9. An electrode structure as claimed in claim 7, wherein the adhesive is an electrically conductive glue.

10. An electrode structure as claimed in any one of the preceding claims, wherein the band-like component of the electrode structure is disposable.

11. An electrode structure as claimed in claim 1, wherein the electrode structure comprises an electronic unit communicating with the electrodes so as to provide heart rate information on the basis of the ECG signal measured with the electrodes.

12. An electrode structure as claimed in claim 11, wherein the electronic unit is arranged in a casing which comprises one or more gripping means for attaching the electronic unit to the band-like component of the electrode structure.

13. An electrode structure as claimed in claim 12, wherein the gripping means are located on that surface of the electronic unit casing which is against the person's skin.

14. An electrode structure as claimed in claim 12, wherein the gripping means form an electric coupling between the electrodes and the electronic unit.

15. A heart rate measuring arrangement for measuring an ECG signal on the skin of a person's chest, wherein

the heart rate measuring arrangement comprises an electrode structure to be placed on the person's chest and a wrist-worn receiver unit, whereby

the electrode structure comprises a band-like component having

an inner surface to be placed against the skin of the person's chest and an outer surface opposite thereto, and

which electrode structure comprises a first electrode at a first end and a second electrode at a second end of the electrode structure,

the inner surface of the electrode structure is an adhesive surface for attaching the electrode structure to the skin of the person's chest, and

the electrode structure is arranged to measure a potential difference between the first and the second electrodes caused by the ECG signal, and

the electrode structure further comprises ECG processing means, which communicate with the electrodes, for measuring the potential difference caused by the ECG signal in the first and the second electrodes and for forming heart rate information on the basis of the measured potential difference, and

the electrode structure further comprises a transmitter for transmitting the heart rate information to a wrist-worn receiver which comprises a receiver for receiving the heart rate information transmitted from the electrode structure, the wrist-worn receiver also comprising a display for presenting the heart rate information.

16. A heart rate measuring arrangement as claimed in claim 15, wherein the band-like component of the electrode structure is a continuous band made of flexible, soft material that fits the skin closely.

17. A heart rate measuring arrangement as claimed in claim 15, wherein the electrode structure comprises an electrically separating part between the first electrode and the second electrode for separating the first electrode and the second electrode electrically from one another.

18. A heart rate measuring arrangement as claimed in claim 15, wherein the electrodes of the electrode structure are of electrically conductive adhesive.

19. A heart rate measuring arrangement as claimed in claim 15, wherein the first electrode and the second electrode of the electrode structure consist of a conductive membrane located at both ends of the electrode structure, at the electrode.

20. A heart rate measuring arrangement as claimed in claim 19, wherein the width of the electrode at both ends of the electrode structure is less than the width of the band-like component.

21. A heart rate measuring arrangement as claimed in claim 19, wherein, at the electrode, on the inner surface against the person's skin there is an electrically conductive adhesive.

22. A heart rate measuring arrangement as claimed in claim 18, wherein the adhesive is an electrically conductive glue.

23. A heart rate measuring arrangement as claimed in claim 21, wherein the adhesive is an electrically conductive glue.

24. A heart rate measuring arrangement as claimed in claim 15, wherein the ECG processing means communicating with the electrodes of the electrode structure comprise an electronic unit for providing heart rate information on the basis of the ECG signal measured with the electrodes.

25. A heart rate measuring arrangement as claimed in claim 24, wherein the electronic unit is arranged in a casing which comprises one or more gripping means for attaching the electronic unit to the band-like component of the electrode structure.

26. A heart rate measuring arrangement as claimed in claim 25, wherein the gripping means are located on that surface of the electronic unit casing which is against the skin of the person.

27. A heart rate measuring arrangement as claimed in claim 25, wherein the gripping means form an electric coupling between the electrodes and the electronic unit.

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